

Appendix A. Search Strategy

Key Question 1 and Key Question 2 Search Strategy

PubMed (3/24/15)

Search	Query	Records
1	((leiomyoma[mh]) OR (fibroma[mh] AND (uterine diseases[mh] OR uterus[mh])))	17656
2	(Uterine[tiab] AND (fibroma*[tiab] OR fibroid*[tiab] OR leiomyoma*[tiab] OR myoma*[tiab] OR fibromyoma*[tiab])) OR (submucous fibroid*[tiab] OR submucosal fibroid*[tiab] OR Intramural fibroids [tiab]) NOT medline[sb]	985
3	#1 OR #2	18621
4	("Mifepristone"[Mesh] OR "ulipristal"[Supplementary Concept] OR "Anti-Inflammatory Agents, Non-Steroidal"[Mesh] OR "Antifibrinolytic Agents"[Mesh] OR "Goserelin"[Mesh] OR "cetrorelix"[Supplementary Concept] OR "Selective Estrogen Receptor Modulators"[Mesh] OR "Levonorgestrel"[Mesh] OR "Nafarelin"[Mesh] OR "Triptorelin Pamoate"[Mesh] OR "Leuprolide"[Mesh])	90459
5	(Mifepristone[tiab] OR Ulipristal acetate[tiab] OR NSAID[tiab] OR antifibrinolytic[tiab] OR Goserelin[tiab] OR cetrorelix acetate[tiab] OR Selective estrogen receptor modulators[tiab] OR SERM[tiab] OR mirena[tiab] OR Ing-ius[tiab] OR levonorgestrel-releasing intrauterine system[tiab] OR management[tiab] OR leuprolide[tiab] OR triptorelin[tiab] OR nafarelin[tiab]) NOT medline[sb]	92082
6	#4 OR #5	182541
7	therapy[sh:noexp] OR drug therapy[mh] OR drug therapy[sh] OR complementary therapies[mh] OR cam[sb] OR Treatment outcome[mh]	4576056
8	surgery[sh] OR surgical procedures, operative[mh] OR embolization, therapeutic[mh]	3058662
9	(Hysterectomy[tiab] OR myomectomy[tiab] OR hysteroscopy[tiab] OR emboliz*[tiab] OR ablation[tiab] OR magnetic resonance guided[tiab] OR focused ultrasound[tiab] OR artery occlusion[tiab] OR UAE[tiab] OR morcellat*[tiab] OR electrosurg*[tiab] OR cryoablation[tiab] OR myolysis[tiab]) NOT medline[sb]	16834
10	#8 OR #9	3075456
11	#6 OR #7 OR #10	6846698
12	#3 AND #11	10260

Notes: “Drug therapy”[mh] includes hormone therapy; “Surgical procedures, operative”[mh] includes ultrasound ablation, embolization, and hysterectomy; **Search lines:** #3=uterine fibroid concept; #6 drug treatment concept; #7=therapy or treatment general concept; #10=surgical and procedural interventions concept; #11=any intervention; #12=any intervention or treatment and fibroid

OVID EMBASE

Query	Records
*uterus myoma/dt, su [Drug Therapy, Surgery] (limited to English language; exclude medline journals; year="1985 -Current")	331

Notes: Retrieved 331; imported 303 after duplicates were discarded.

Key Question 3 Search Strategy

PubMed (1/26/2016)

Search	Query	Records
1	25016181 OR 24347933 OR 24012921 OR 23962573 OR 23189178 OR 23053310 OR 22905461 OR 22732808 OR 22626269 OR 22472335 OR 22142874 OR 22095838	12
2	Similar articles for PubMed (Select 12 documents) Filters: Publication date from 2014/03/01 to 2016/12/31	400

Notes: After duplicates removed, this literature strategy contributed 319 unique records.

Key Question 4 Search Strategy

Table X. PubMed (3/13/15)

Search	Query	Records
1	morcellation	445
2	morcellat* AND uterine	256
3	morcellat*	562
4	("Electrosurgery/adverse effects"[Mesh]) OR "Uterine Myomectomy/adverse effects"[MeSH] OR morcellat*	1251
5	("Electrosurgery/adverse effects"[Mesh] AND uterine) OR "Uterine Myomectomy/adverse effects"[MeSH] OR morcellat*	742

Table X. PubMed (10/21/15)

Search	Query	Records
1	morcellation	520
2	morcellat* AND uterine	325
3	morcellat*	648
4	("Electrosurgery/adverse effects"[Mesh]) OR "Uterine Myomectomy/adverse effects"[MeSH] OR morcellat*	1374
5	("Electrosurgery/adverse effects"[Mesh] AND uterine) OR "Uterine Myomectomy/adverse effects"[MeSH] OR morcellat*	850

Notes: After duplicates removed, this literature search update added 103 records.

Appendix B. Population, Intervention, Comparator, Outcomes, Timing, and Setting

PICOTS	Criteria and Key Question(s)
Population	<ul style="list-style-type: none"> • Women who are being treated for uterine fibroids (KQs 1-4)
Intervention(s)	<ul style="list-style-type: none"> • Surgical (KQs 1-4) • Procedural (KQs 1, 2) • Medical / Pharmacologic (KQs 1, 2) • Morcellation (KQs 1-4)
Comparator	<ul style="list-style-type: none"> • Inactive treatment including wait list control, expectant management, or placebo • Active treatment
Outcomes	<p><u>Intermediate outcomes (KQ 1)</u></p> <ul style="list-style-type: none"> • Technical success • Conversion to alternate operative procedure • Estimated blood loss • Wound healing status • Length of stay • Readmission/reoperation • Return to usual activities <p><u>Adverse effects / Harms (KQs 1, 3)</u></p> <ul style="list-style-type: none"> • Transfusion • Unplanned hysterectomy • Perforation of organs • Cancer dissemination • Misdirected embolization / non-target tissue embolization • Ovarian failure • Other serious adverse events <p><u>Final health outcomes (KQ 1)</u></p> <ul style="list-style-type: none"> • Symptom status • Desired fertility status • Pregnancy outcomes • Sexual function • Fibroid characteristics • Fibroid recurrence • Subsequent treatment for fibroids • Satisfaction with outcomes
Timing	Any length of followup (KQs 1-4)
Setting	<p>Clinical setting in countries with health care systems similar to the U.S. (defined as inclusion as a Very High Human Development country on the United Nations Development Programme Human Development Index (KQs1-4))</p> <p><i>Countries include: Albania, Algeria, Andorra, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahamas, Bahrain, Barbados, Belarus, Belgium, Belize, Bosnia and Herzegovina, Brazil, Brunei Darussalam, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Dominica, Dominican Republic, Ecuador, Estonia, Fiji, Finland, France, Georgia, Germany, Greece, Grenada, Hong Kong, China (SAR), Hungary, Iceland, Iran (Islamic Republic of), Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Korea (Republic of), Kuwait, Latvia, Lebanon, Libya, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Montenegro, Netherlands, New Zealand, Norway, Oman, Palau, Panama, Peru, Poland, Portugal, Qatar, Romania, Russian</i></p>

PICOTS	Criteria and Key Question(s)
	<i>Federation, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Saudi Arabia, Serbia, Seychelles, Singapore, Slovakia, Slovenia, Spain, Sri Lanka, Suriname, Sweden, Switzerland, Thailand, The former Yugoslav Republic of Macedonia, Tonga, Trinidad and Tobago, Tunisia, Turkey, Ukraine, United Arab Emirates, United Kingdom, United States, Uruguay, Venezuela</i>

Abbreviations: KQ=key question;

Appendix C. Screening Forms

Key Question 1 Literature Screening Forms

Screening Form: Level 1

Question Text	Choice(s)	Code
1. Study evaluates a surgical or procedural or medical intervention(s) for women with uterine fibroids (If "NO," answer question 1a, submit this form, and move to next. If paper addresses morcellation harms, check Retain below before submitting.)	Yes	Yes
	No	X-1
	Cannot Determine	Unclear
1a. If no, the study evaluates (check all that apply)	Basic science	X-1a
	Genetics/etiology	X-1b
	Imaging/diagnosis	X-1c
	Pathophysiology/physiology	X-1d
	Pre-operative adjuncts to shrink fibroids or improve anemia	X-1e
	Risk factors	X-1f
	Case report	X-1g
	Other	X-1h
	Not uterine fibroid	X-1i
2. Paper reports original research (i.e., paper is not a review, editorial, commentary, letter to editor, etc.)	Yes	Yes
	No	X-2
	Cannot Determine	Unclear
3. Eligible study design: randomized controlled trial	Yes	Yes
	No	X-3
	Cannot Determine	Unclear
3a. If no, please select study design	Prospective or retrospective cohort study	X-3a
	Non-randomized trial	X-3b
	Case series	X-3c
	Case report	X-3d
	Case-control	X-3e
	Other	X-3f
Screener Comments:		
Retain for:	Background/Discussion	Bkg
	Review of references	Refs
	Harms/AE data	Harms
	Other	Oth

Screening Form: Level 2

Question Text	Choice(s)	Code
1. Paper reports original research (i.e., paper is not a review, editorial, commentary, letter to editor, etc.) NOTE: If the publication appears relevant to the topic, consider whether it should be retained for "review for references" (see check boxes below the form). These publications will be flagged for review, but not promoted for full text screening.	Yes	Yes
	No	X-2
2. Study evaluates an intervention/treatment for uterine fibroids	Yes	Yes
	No	X-1
2a. If no, the study evaluates (check all that apply)	Basic science	X-1a
Reason	Genetics/etiology	X-1b
	Imaging/diagnosis	X-1c
	Pathophysiology/physiology	X-1d
	Pre-operative adjuncts to shrink fibroids or improve anemia	X-1e
	Risk factors	X-1f
	Case report	X-1g
	Other	X-1h
	Not uterine fibroid	X-1i
3. Eligible study design: randomized controlled trial	Yes	Yes
	No	X-3
3a. If no, please select study design	Prospective or retrospective cohort study	X-3a
	Non-randomized trial	X-3b
	Case series	X-3c
	Case report	X-3d
	Case-control	X-3e
	Other	X-3f
4. The study population is women with uterine fibroids or, for studies of mixed conditions, data is reported separately for women with uterine fibroids.	Yes	Yes
	No	X-5
5. Eligible setting: Any setting (clinic, hospital) in countries with health care systems similar to the U.S.	Yes	Yes
	No	X-4
6. Reports outcome(s) of interest	Yes	Yes
	No	X-6
Intermediate Outcomes	Technical success	IO01
	Conversion to alternate operative procedure	IO02
	Estimated blood loss	IO03
	Wound healing status	IO04
	Length of stay	IO05
	Readmission or reoperation	IO06
	Return to usual activities	IO07
Final Health Outcomes	Symptom status	FH01
	Desired fertility status	FH02
	Pregnancy outcome	FH03
	Sexual function	FH04

Question Text	Choice(s)	Code
	Fibroid characteristic	FH05
	Fibroid recurrence	FH06
	Subsequent treatment for uterine fibroids	FH07
	Satisfaction with outcomes	FH08
Adverse effects / Harms	Transfusion	AE01
	Unplanned hysterectomy	AE02
	Perforation of organs	AE03
	Misdirected embolization	AE04
	Cancer dissemination	AE05
	Other	AE06
7. Addresses Key Question(s) If the aim of the study is to assess adhesion status, evaluate the preoperative or adjunctive medical treatment to minimize intraoperative blood loss or postoperative pain, or to report operative technique, time, or cost, check "no" and provide a brief explanation.	Yes	Yes
	No	X-7
Reason	Text	
Check one or more Key Question	(KQ1) What is the comparative effectiveness of treatments for uterine fibroids?	KQ1
	(KQ2) Does treatment effectiveness differ by patient or fibroid characteristics?	KQ2
	(KQ3) What is the risk of harm from morcellation of uterine fibroids at the time of myomectomy or hysterectomy?	KQ3
	(KQ4) Does risk of harm from morcellation differ by patient or fibroid characteristics?	KQ4
Check one or more intervention or treatment category	Hysterectomy	HYS
	Myomectomy	MYO
	Uterine artery embolization	UAE
	Ablative procedures (e.g., magnetic resonance-guided focused ultrasound [MRgFUS], cryoablation)	ABL
	Progestin-containing intrauterine devices	IUD
	Medication to resolve symptoms or reduce size of fibroids	MED
Type of comparator(s) in the study	Inactive control (e.g., expectant management, placebo)	IAC
	Other	OTH
	Alternate intervention/treatment	ALT
Comparator category	Hysterectomy	HYS
	Myomectomy	MYO
	Uterine artery embolization	UAE
	Ablative procedure (e.g., magnetic	ABL

Question Text	Choice(s)	Code
	resonance-guided focused ultrasound [MRgFUS], cryoablation)	
	Progestin-containing intrauterine devices	IUD
	Medication to resolve symptoms or reduce size of fibroids	MED
Retain	Background	Bkg
	Review of references	Refs
	Harms data	Harms
	Other	Oth
Comments	Text	
Part of a family	Yes	Yes
	No	No
	Unclear	Unclear
Related Ref ID(s):	Text	
Administrative	Unavailable	X-10
	Non-English	X-11
	Duplicate	X-12

Key Question 3 Literature Screening Forms

Screening Form: Level 1

Question Text	Choice(s)	Code
1. Reports original research (includes analysis of clinical or administrative data).	Yes	Yes
	No	X-1
	Unclear	UC
2. Population is women with uterine fibroids.	Yes	Yes
	No	X-2
3. Publication includes (or reports data from) 5 or more patients treated for uterine fibroids.	Yes	Yes
	No	X-4
	Unclear	UC
4. Publication reports the histopathological status of tumors from all women treated for uterine fibroids.	Yes	Yes
	No	X-3
	Unclear	UC
Number of women with uterine fibroids:	<i>text</i>	-
Number with confirmed leiomyosarcoma:	<i>text</i>	-
Leiomyosarcoma rate:	<i>text</i>	-
Retain for: Review of references	<input type="checkbox"/>	REFS
Retain for: Team Review	<input type="checkbox"/>	TEAM
Retain for: Other	<input type="checkbox"/>	OTH

Screening Form: Level 2

Question Text	Choice(s)	Code
1. Reports original research (includes analysis of clinical or administrative data).	Yes	Yes
	No	X-1
2. Population is women with uterine fibroids.	Yes	Yes
	No	X-2
3. Publication includes (or reports data from) 5 or more patients treated for uterine fibroids.	Yes	Yes
	No	X-4
4. Publication reports the histopathological status of tumors from all women treated for uterine fibroids.	Yes	Yes
	No	X-3
Number of women with uterine fibroids:	<i>Text</i>	-
Number with confirmed leiomyosarcoma:	<i>Text</i>	-
Leiomyosarcoma rate:	<i>Text</i>	-
Retain for: Review of references	<i>Checkbox</i>	REFS
Retain for: Team Review	<i>Checkbox</i>	TEAM
Retain for: Other	<i>Checkbox</i>	OTH
Comments:	<i>Text</i>	-
Admin: Duplicate	<i>Checkbox</i>	X-11
Admin: Unavailable	<i>Checkbox</i>	X-12
Admin: Non-English	<i>Checkbox</i>	X-13
Admin: Published before 2014	<i>Checkbox</i>	X-14

Key Question 4 Literature Screening Forms

Screening Form: Level 1

Question Text	Choice(s)	Code
1. Reports original research (includes analysis of clinical or administrative data).	Yes	Yes
	No	X-1
	Unclear	Unclear
2. Population is women with uterine fibroids.	Yes	Yes
	No	X-2
3. Publication includes 5 or more patients (or data from patients) treated for uterine fibroids.	Yes	Yes
	No	X-3
	Unclear	Unclear
Number of patients included /number of clinical or administrative records analyzed:	<i>Text</i>	
4. The publication reports morcellator use.	Yes	Yes
	No	X-4
	Unclear	Unclear
5. The publication reports outcome(s) related to leiomyosarcoma subsequent to treatment for uterine fibroids.	Yes	Yes
	No	X-5
Check "yes" when the publication describes patients treated for uterine fibroids and follows those individuals forward in time. A publication that reports tumor pathology at time of treatment only (i.e., postoperative histopathologic information) should not be included unless it also reports subsequent outcomes such as residual disease, recurrence, survival, etc. Do not include papers that identify cases of leiomyosarcoma or uterine malignancy and look back to ascertain the time, type, and indication for initial treatment.	Unclear	Unclear
Brief description of relevance of findings to KQ 4	<i>Text</i>	-
Brief description of reason for exclusion:	<i>Text</i>	-
Retain for: Background	<i>Checkbox</i>	BKG
Retain for: Review of references	<i>Checkbox</i>	REFS
Retain for: Team Review	<i>Checkbox</i>	TEAM
Retain for: LMS prevalence *	<i>Checkbox</i>	LMS
Retain for: Other	<i>Checkbox</i>	OTH

Screening Form: Level 2

Question Text	Choice(s)	Code
1. Paper reports original research (i.e., paper is not a review, editorial, commentary, letter to editor, etc.)	Yes	Yes
	No	X-1
2. Study reports use of morcellation or en bloc removal of the uterus or uterine fibroid.	Yes	Yes
	No	X-2
3. Eligible study design: case series, cohort, or trial Do not include studies that identify cases of leiomyosarcoma or uterine malignancy and look back at treatment/ exposure status	Yes	Yes
	No	X-3
3a. If no, please select study design / article type:		
Article type: Case report	<i>Checkbox</i>	X-3a
Article type: Literature review	<i>Checkbox</i>	X-3b
Article type: Surgical technique	<i>Checkbox</i>	X-3c
Article type: Retrospective cohort*	<i>Checkbox</i>	X-3e
Article type: Other	<i>Checkbox</i>	X-3d
4. The paper includes 5 or more patients treated for uterine fibroids.	Yes	Yes
	No	X-4
5. The publication reports outcome(s) related to leiomyosarcoma subsequent to treatment for uterine fibroids. Check "yes" when the publication describes patients treated for uterine fibroids and follows those individuals forward in time. A publication that reports tumor pathology at time of treatment only (i.e., postoperative histopathologic information) should not be included unless it also reports subsequent outcomes such as residual disease, recurrence, survival, etc. Do not include papers that identify cases of leiomyosarcoma or uterine malignancy and look back to ascertain the time, type, and indication for initial treatment.	Yes	Yes
	No	X-5
Retain for: Background	<i>Checkbox</i>	BKG
Retain for: Review of references	<i>Checkbox</i>	REFS
Retain for: LMS prevalence (KQ3)	<i>Checkbox</i>	LMS
Other	<i>Checkbox</i>	OTH
Comments	<i>Text</i>	
Related Ref ID(s):	<i>Text</i>	
Admin: Unavailable	<i>Checkbox</i>	X-10
Admin: Non-English	<i>Checkbox</i>	X-11
Admin: Duplicate	<i>Checkbox</i>	X-12

Appendix D. Reasons for Exclusion

Reasons for exclusion: Key Question 1 (n = 1,121)

Exclusion Code	Exclusion Reason	Count
X-1	Does not include an intervention or treatment for uterine fibroids <ul style="list-style-type: none"> - <i>Basic science (X-1a)</i> - <i>Genetics/etiology (X-1b)</i> - <i>Imaging/diagnosis (X-1c)</i> - <i>Pathophysiology/physiology (X-1d)</i> - <i>Pre-operative adjuncts to shrink fibroids or improve anemia (X-1e)</i> - <i>Risk factors (X-1f)</i> - <i>Case report (X-1g)</i> - <i>Other (X-1h)</i> - <i>Not uterine fibroid (X-1i)</i> 	520
X-2	Not original research	520
X-3	Not an eligible study design <ul style="list-style-type: none"> - <i>Prospective or retrospective cohort study (X-3a)</i> - <i>Non-randomized trial (X-3b)</i> - <i>Case series (X-3c)</i> - <i>Case report (X-3d)</i> - <i>Case-control (X-3e)</i> - <i>Other (X-3f)</i> 	456
X-4	Not conducted in an eligible country	35
X-5	Population is not women with uterine fibroids or does not report data separately from mixed population	52
X-6	Does not report an outcome of interest	100
X-7	Does not address a Key Question	152
X-10	Unavailable	0
X-11	Non-English	107
X-12	Duplicate	0

*Total count exceeds number of records as records can be excluded for more than one reason

Records excluded at full-text screening for Key Question 1 (n = 1,121)

References listed alphabetically by first author last name

1. Uterine fibroids: medical treatment or surgery? Lancet 1986 Nov 22;2(8517):1197. PMID: 2877334. **X-2**
2. [First National Enantone-Gyn Symposium. Advances in the therapy of endometriosis and uterine myomas. Heidelberg, 2 November 1991]. Gynakologe 1991 Dec;24(6 Suppl):1-12. PMID: 1685723. **X-2**
3. Recurrence of fibroids after myomectomy. Lancet 1991 Aug 31;338(8766):548. PMID: 1678808. **X-2**
4. Pretreatment with Zoladex improves surgery for uterine fibroids. Oncology (Williston Park) 1991 Jan;5(1):94. PMID: 1828691. **X-2**
5. Prophylaxis of pelvic sidewall adhesions with Gore-Tex surgical membrane: a multicenter clinical investigation. The Surgical Membrane Study Group. Fertil Steril 1992 Apr;57(4):921-3. PMID: 1555708. **X-1, X-1h, X-3, X-3f**
6. An expanded polytetrafluoroethylene barrier (Gore-Tex Surgical Membrane) reduces post-myomectomy adhesion formation. The Myomectomy Adhesion Multicenter Study Group. Fertil Steril 1995 Mar;63(3):491-3. PMID: 7851575. **X-6, X-7**
7. ACOG criteria set. Gonadotropin-releasing hormone agonists for preoperative treatment of leiomyomata. American College of Obstetricians and Gynecologists Committee on Quality Assessment. Int J Gynaecol Obstet 1996 Feb;52(2):213-4. PMID: 8855113. **X-2**
8. [Radiologists may prevent hysterectomy in some patients]. Rofo 1997 Nov;167(5):M39. PMID: 9440884. **X-2, X-11**
9. Options for hysterectomy. Health News 1998 Oct 25;4(13):1-2. PMID: 9803170. **X-2**
10. Treating fibroids. Harv Womens Health Watch 1998 Apr;5(8):2-3. PMID: 9577267. **X-2**
11. Patient death raises issue of new technology in ORs. OR Manager 1999 Jan;15(1):1, 8-9. PMID: 10345129. **X-2**
12. Procedure minimizes need for hysterectomies. Rep Med Guidel Outcomes Res 2000 Aug 3;11(16):8-10. PMID: 11799996. **X-2**
13. The future of women's health. Harv Womens Health Watch 2000 Jan;7(5):4-6. PMID: 10594969. **X-2**
14. Uterine artery embolization for leiomyomata. Clin Privil White Pap 2001 Jul 19(63):1-7. PMID: 11715990. **X-2**
15. Uterine artery embolization for treatment of symptomatic uterine fibroids. TEC Bull (Online) 2002 Jul 8;19(2):37-9. PMID: 12166477. **X-1, X-2**
16. Patient page. Uterine fibroid embolization. Radiol Technol 2003 Nov-Dec;75(2):176. PMID: 14671837. **X-2**
17. [Endometriosis and differelin]. Akush Ginekol (Sofia) 2003;42 Suppl 1:27-8. PMID: 12899124. **X-1, X-1i, X-2**
18. Ultrasound treatment zaps fibroids. Health News 2004 Aug;10(8):2. PMID: 15551451. **X-2**
19. Myomas and reproductive function. Fertil Steril 2004 Sep;82 Suppl 1:S111-6. doi: 10.1016/j.fertnstert.2004.05.061. PMID: 15363705. **X-2**
20. Magnetic resonance-guided focused ultrasound therapy for symptomatic uterine fibroids. Technol Eval Cent Assess Program Exec Summ 2005 Oct;20(10):1-3. PMID: 16267949. **X-2**
21. [Recommendations of good practice: drug therapy for fibroma of uterus (October 2004)]. Gynecol Obstet Fertil 2005 Jul-Aug;33(7-8):547-52. PMID: 16106573. **X-2**

22. Can you tell me about the new device the FDA has approved for treating uterine fibroids? Mayo Clin Womens Healthsource 2005 Apr;9(4):8. PMID: 15891684. **X-2**
23. Uterine artery embolization for fibroids. Med Lett Drugs Ther 2005 Apr 11;47(1206):31-2. PMID: 15821634. **X-2**
24. Noninvasive treatment for uterine fibroids. FDA Consum 2005 Jan-Feb;39(1):4. PMID: 15803583. **X-2**
25. Myomas and reproductive function. Fertil Steril 2006 Nov;86(5 Suppl 1):S194-9. doi: 10.1016/j.fertnstert.2006.08.026. PMID: 17055821. **X-2**
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27. Treating uterine fibroids. New therapies provide more choices. Mayo Clin Womens Healthsource 2006 May;10(5):4-5. PMID: 16585924. **X-1, X-1h, X-2, X-3, X-3f, X-5**
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29. Treating uterine fibroids using MR-guided ultrasound. Manag Care 2011 Dec;20(12):12-3. PMID: 22259871. **X-2**
30. [Diagnosis and treatment of uterine myomatosis]. Ginecol Obstet Mex 2011 Nov;79(11):711-8. PMID: 22168118. **X-2**
31. Uterine artery embolization. Clin Priv White Pap 2012 Jul(63):1-12. PMID: 23082340. **X-2**
32. An emergency contraceptive pill helps treat fibroids. Harv Womens Health Watch 2012 Apr;19(8):6. PMID: 22649808. **X-2**
33. Oral sciences research leads to uterine fibroid treatment. J Can Dent Assoc 2013;79:d59. PMID: 23763737. **X-2**
34. High-intensity focused ultrasound effective on submucosal fibroids. Health Devices 2013 Apr;42(4):136-7. PMID: 23687674. **X-2**
35. Uterine artery embolisation: an alternative to surgery? Prescribe Int 2014 May;23(149):133. PMID: 24926521. **X-2**
36. Patient safety must be a priority in all aspects of care. Lancet Oncol 2014 Feb;15(2):123. doi: 10.1016/s1470-2045(14)70042-7. PMID: 24480553. **X-2, X-3, X-4, X-6, X-7**
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38. Abd El Fatah GH, Elhamamsy MH, Abd El Khalek MS, et al.; Fibroid therapy. Internet Journal of Gynecology and Obstetrics 2010;13(1). PMID: 2010367869. **X-4**
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Reasons for exclusion: Key Question 3 (n = 392)

Exclusion Code	Exclusion Reason	Count*
X-1	Not original research	117
X-2	Not women with fibroids	100
X-3	Does not report the histopathological status of tumors from all women treated for uterine fibroids	270
X-4	Does not include 5 or more patients	142
X-11	Duplicate	0
X-12	Unavailable	0
X-13	Non-english	1
X-14	Published before 2014	4

*Total count exceeds number of records as records can be excluded for more than one reason

Records excluded at abstract or full text screening for Key Question 3 (n = 392)

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Reasons for exclusion: Key Question 4 (n = 856)

Exclusion Code	Exclusion Reason	Count*
L1: X-1; L2: X-1	Not original research	229
L1: X-2	Not women with fibroids	298
L1: X-3; L2: X-4	Does not include 5 or more patients treated for uterine fibroids	444
L1: X-4; L2: X-2	Does not report morcellator use	180
L1: X-5; L2: X-5	Does not report outcome(s) related to leiomyosarcoma subsequent to treatment for uterine fibroids	501
L2: X-3	Ineligible study design or article type	9
L2: X-10	Unavailable	1
L2: X-11	Non-English	1
L2: X-12	Duplicate	0

*Total count exceeds number of records as records can be excluded for more than one reason

Records excluded at abstract or full text screening for Key Question Key Question 4 (n = 856)

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837. Wu SD, Lesani OA, Zhao LC, et al.; A multi-institutional study on the safety and efficacy of specimen morcellation after laparoscopic radical nephrectomy for clinical stage T1 or T2 renal cell carcinoma. J Endourol 2009 Sep;23(9):1513-8. doi: 10.1089/end.2009.0387. PMID: 19694517. **LI: X-2, X-3, X-5**
838. Wyman A, Fuhrig L, Bedaiwy MA, et al.; A Novel Technique for Transvaginal Retrieval of Enlarged Pelvic Viscera during Minimally Invasive Surgery. Minim Invasive Surg 2012;2012:454120. doi: 10.1155/2012/454120. PMID: 22811899. **LI: X-1, X-3, X-4, X-5**
839. Xia EL, Duan H, Zhang J, et al.; [Analysis of 16 cases of uterine perforation during hysteroscopic electro-surgeries]. Zhonghua Fu Chan Ke Za Zhi 2003 May;38(5):280-3. PMID: 12895311. **LI: X-2, X-5**
840. Xia SJ; Two-micron (thulium) laser resection of the prostate-tangerine technique: a new method for BPH treatment. Asian J Androl 2009 May;11(3):277-81. doi: 10.1038/aj.2009.17. PMID: 19398957. **LI: X-2, X-3**
841. Xia SJ, Zhu J, Lu J, et al.; [The treatment of benign prostatic hyperplasia by means of transurethral holmium laser enucleation]. Zhonghua Nan Ke Xue 2003;9(4):257-9. PMID: 12931364. **LI: X-2, X-3**
842. Xu A, Zou Y, Li B, et al.; A randomized trial comparing diode laser enucleation of the prostate with plasmakinetic enucleation and resection of the prostate for the treatment of benign prostatic hyperplasia. J Endourol 2013 Oct;27(10):1254-60. doi: 10.1089/end.2013.0107. PMID: 23879477. **LI: X-2, X-3**
843. Yanazume S, Tsuji T, Yoshioka T, et al.; Large parasitic myomas in abdominal subcutaneous adipose tissue along a previous myomectomy scar. J Obstet Gynaecol Res 2012 May;38(5):875-9. doi: 10.1111/j.1447-0756.2011.01784.x. PMID: 22413957. **LI: X-4, X-5**
844. Yang R, Xu T, Fu Y, et al.; Leiomyomatosis peritonealis disseminata associated with

- endometriosis: A case report and review of the literature. *Oncol Lett* 2015 Feb;9(2):717-20. doi: 10.3892/ol.2014.2741. PMID: 25621042. **LI: X-5**
845. Yang Y, Tan X, Li P; [Clinical observation of hysteroscopic electric resection: an analysis of 36 patients with abnormal uterine bleeding]. *Zhonghua Fu Chan Ke Za Zhi* 1999 Aug;34(8):482-4. PMID: 11360600. **LI: X-4, X-5**
846. Yen YK, Liu WM, Yuan CC, et al.; Comparison of two procedures for laparoscopic-assisted vaginal hysterectomy of large myomatous uterus. *J Am Assoc Gynecol Laparosc* 2002 Feb;9(1):63-9. PMID: 11821608. **LI: X-5,**
INCLUDE
847. Yoon G, Kim TJ, Lee YY, et al.; Single-port access subtotal hysterectomy with transcervical morcellation: a pilot study. *J Minim Invasive Gynecol* 2010 Jan-Feb;17(1):78-81. doi: 10.1016/j.jmig.2009.09.018. PMID: 19926345. **LI: X-5**
848. Yoshida A, Nii S, Matsushita H, et al.; Parasitic myoma in women after laparoscopic myomectomy: A late sequela of morcellation? *J Obstet Gynaecol* 2014 Aug 11:1-2. doi: 10.3109/01443615.2014.948404. PMID: 25111124. **LI: X-5**
849. Zeng SY, Liang MR, Li LY, et al.; Comparison of the efficacy and complications of different surgical methods for cervical intraepithelial neoplasia. *Eur J Gynaecol Oncol* 2012;33(3):257-60. PMID: 22873094. **LI: X-3, X-4**
850. Zhang C, Havrilesky LJ, Broadwater G, et al.; Relationship between minimally invasive hysterectomy, pelvic cytology, and lymph vascular space invasion: a single institution study of 458 patients. *Gynecol Oncol* 2014 May;133(2):211-5. doi: 10.1016/j.ygyno.2014.02.025. PMID: 24582867. **LI: X-4, X-5**
851. Zhang F, Shao Q, Herrmann TR, et al.; Thulium laser versus holmium laser transurethral enucleation of the prostate: 18-month follow-up data of a single center. *Urology* 2012 Apr;79(4):869-74. doi: 10.1016/j.urology.2011.12.018. PMID: 22342411. **LI: X-2, X-3**
852. Zhang JT, Wang HB, Liu YF, et al.; Laparoscopic splenectomy in goats. *Vet Surg* 2009 Apr;38(3):406-10. doi: 10.1111/j.1532-950X.2009.00507.x. PMID: 19573106. **LI: X-2, X-3, X-5**
853. Zhang P, Song K, Li L, et al.; Application of simultaneous morcellation in situ in laparoscopic myomectomy of larger uterine leiomyomas. *Med Princ Pract* 2011;20(5):455-8. doi: 10.1159/000327671. PMID: 21757936. **LI: X-3, X-5**
854. Zhang W, Yuan JJ, Kan QC, et al.; Influence of CYP3A5*3 polymorphism and interaction between CYP3A5*3 and CYP3A4*1G polymorphisms on post-operative fentanyl analgesia in Chinese patients undergoing gynaecological surgery. *Eur J Anaesthesiol* 2011 Apr;28(4):245-50. PMID: 21513075. **LI: X-4, X-5**
855. Zografos GN, Vasiliadis G, Farfaras AN, et al.; Laparoscopic surgery for malignant adrenal tumors. *Jsls* 2009 Apr-Jun;13(2):196-202. PMID: 19660215. **LI: X-1, X-3**
856. Zullo F, Falbo A, Iuliano A, et al.; Randomized controlled study comparing the Gynecare Morcellex and Rotocut G1 tissue morcellators. *J Minim Invasive Gynecol* 2010 Mar-Apr;17(2):192-9. doi: 10.1016/j.jmig.2009.11.009. PMID: 20226407. **LI: X-5**

Appendix E: Studies Characteristics

Key Question 1 and Key Question 2

Studies included for Key Question 1 and Key Question 2 (n = 109)

Citation	Funding	Randomized	Country	Arms	KQ1	KQ2	Primary Study	Expectant Management	Medical	Procedural	Surgical
Alessandri F et al. (2006) ¹	NR	148	Italy	2	Yes	No	Yes	No	No	No	Yes
Ananthakrishnan G et al. (2013) ²	NA	157	Multiple	2	Yes	Yes	No	No	No	Yes	Yes
Ardovino M et al. (2013) ³	NR	170	Italy	2	Yes	No	Yes	No	No	No	Yes
Benassi L et al. (2002) ⁴	NR	119	Italy	2	Yes	No	Yes	No	No	No	Yes
Bilhim T et al. (2011) ⁵	NR	160	Portugal	2	Yes	No	Yes	No	No	Yes	No
Broekmans FJ et al. (1996) ⁶	Ind	27	Netherlands	3	Yes	No	Yes	No	Yes	No	No
Brucker SY et al. (2014) ⁷	Ind	51	Germany	2	Yes	No	Yes	No	No	Yes	Yes
Carbonell Esteve JL et al. (2008) ⁸	NGO	100	Cuba	2	Yes	No	Yes	No	Yes	No	No
Carbonell JL et al. (2013) ⁹	Ind	220	Cuba	2	Yes	No	Yes	No	Yes	No	No
Carbonell JL et al. (2013) ¹⁰	Ind	70	Cuba	2	Yes	No	Yes	No	Yes	No	No
Carr BR et al. (1993) ¹¹	Govt	16	United States	2	Yes	No	Yes	No	Yes	No	No
Casini ML et al. (2006) ¹²	NR	181	Italy	2	Yes	Yes	Yes	Yes	No	No	Yes
Chwalisz K et al. (2007) ¹³	Ind	129	Multiple	4	Yes	No	Yes	Yes	Yes	No	No
Cincinelli E et al. (2009) ¹⁴	NR	80	Italy	2	Yes	No	Yes	No	No	No	Yes
Costantini S et al. (1990) ¹⁵	Other	42	Italy	2	Yes	No	Yes	No	Yes	No	No
Cunningham E et al. (2008) ¹⁶	NGO	16	United States	2	Yes	No	Yes	No	No	Yes	No
Donnez J et al. (2014) ¹⁷	Ind	209	Multiple	2	Yes	No	Yes	No	Yes	No	No
Donnez J et al. (2015) ¹⁸	Ind	451	Multiple	2	Yes	No	Yes	No	Yes	No	No
Eder S et al. (2013) ¹⁹	Ind	147	United States	2	Yes	No	Yes	Yes	Yes	No	No
Edwards RD et al. (2007) ²⁰	Govt	157	United Kingdom	2	Yes	Yes	Yes	No	No	Yes	Yes
Eisinger SH et al. (2003) ²¹	NGO	40	United States	2	Yes	Yes	Yes	No	Yes	No	No
Eisinger SH et al. (2005) ²²	NA	40	United States	2	Yes	Yes	No	No	Yes	No	No
Esteve JL et al. (2012) ²³	Ind	176	Cuba	2	Yes	No	Yes	No	Yes	No	No
Esteve JL et al. (2013) ²⁴	Ind	124	Cuba	2	Yes	No	Yes	Yes	Yes	No	No
Fedele L et al. (1991) ²⁵	NR	42	Italy	2	Yes	No	Yes	No	Yes	No	Yes

Citation	Funding	Randomized	Country	Arms	KQ1	KQ2	Primary Study	Expectant Management	Medical	Procedural	Surgical
Fedele L et al. (2000) ²⁶	NR	38	Italy	2	Yes	No	Yes	No	Yes	No	No
Ferrari MM et al. (2000) ²⁷	NR	62	Italy	2	Yes	No	Yes	No	No	No	Yes
Fiscella K et al. (2006) ²⁸	Govt	42	United States	2	Yes	No	Yes	Yes	Yes	No	No
Friedman AJ et al. (1988) ²⁹	Multiple	16	United States	2	Yes	No	Yes	No	Yes	No	No
Friedman AJ et al. (1989) ³⁰	Multiple	38	United States	2	Yes	No	Yes	Yes	Yes	No	No
Friedman AJ et al. (1991) ³¹	Ind	128	United States	2	Yes	No	Yes	Yes	Yes	No	No
Friedman AJ et al. (1993) ³²	Multiple	51	United States	2	Yes	No	Yes	No	Yes	No	No
Friedman AJ et al. (1994) ³³	NA	51	United States	2	Yes	No	No	No	Yes	No	No
Gregoriou O et al. (1997) ³⁴	NR	40	Greece	2	Yes	No	Yes	Yes	Yes	No	No
Hald K et al. (2007) ³⁵	NR	66	Norway	2	Yes	No	Yes	No	No	Yes	No
Hald K et al. (2009) ³⁶	NA	66	Norway	2	Yes	No	No	No	No	Yes	No
Hehenkamp WJ et al. (2005) ³⁷	Multiple	177	Netherlands	2	Yes	Yes	Yes	No	No	Yes	Yes
Hehenkamp WJ et al. (2006) ³⁸	NA	177	Netherlands	2	Yes	No	No	No	No	Yes	Yes
Hehenkamp WJ et al. (2007) ³⁹	NA	177	Netherlands	2	Yes	No	No	No	No	Yes	Yes
Hehenkamp WJ et al. (2007) ⁴⁰	NA	177	Netherlands	2	Yes	No	No	No	No	Yes	Yes
Hehenkamp WJ et al. (2008) ⁴¹	NA	177	Netherlands	2	Yes	No	No	No	No	Yes	Yes
Hwang JL et al. (2002) ⁴²	NR	90	Taiwan	3	Yes	No	Yes	No	No	No	Yes
Jiang N et al. (2014) ⁴³	Govt	80	China	2	Yes	No	Yes	No	No	Yes	No
Jirecek S et al. (2004) ⁴⁴	NR	25	Austria	2	Yes	No	Yes	Yes	Yes	No	No
Jun F et al. (2012) ⁴⁵	NR	127	China	2	Yes	No	Yes	No	No	Yes	Yes
Levens E et al. (2008) ⁴⁶	Multiple	22	United States	3	Yes	No	Yes	Yes	Yes	No	No
Liu M et al. (2011) ⁴⁷	NR	359	China	2	Yes	No	Yes	No	No	No	Yes
Mais V et al. (1996) ⁴⁸	NR	40	Italy	2	Yes	No	Yes	No	No	No	Yes
Manyonda IT et al. (2012) ⁴⁹	Other	163	United Kingdom	2	Yes	No	Yes	No	No	Yes	Yes
Mara M et al. (2006) ⁵⁰	Govt	63	Czech Republic	2	Yes	No	Yes	No	No	Yes	Yes
Mara M et al. (2008) ⁵¹	NA	121	Czech Republic	2	Yes	No	No	No	No	Yes	Yes
Melli MS et al. (2007) ⁵²	Other	50	Iran	2	Yes	No	Yes	No	Yes	No	No
Meng X et al. (2010) ⁵³	NR	100	China	2	Yes	Yes	Yes	No	No	Yes	No
Morris EP et al. (2008) ⁵⁴	Ind	75	United Kingdom	3	Yes	No	Yes	No	Yes	No	No

Citation	Funding	Randomized	Country	Arms	KQ1	KQ2	Primary Study	Expectant Management	Medical	Procedural	Surgical
Moss JG et al. (2011) ⁵⁵	NA	157	United Kingdom	2	Yes	No	No	No	No	Yes	Yes
Nieman LK et al. (2011) ⁵⁶	Govt	42	United States	2	Yes	No	Yes	Yes	Yes	No	No
Orsi F et al. (2015) ⁵⁷	NR	33	Italy	2	Yes	No	Yes	No	No	Yes	No
Palomba S et al. (1998) ⁵⁸	Other	50	Italy	2	Yes	No	Yes	No	Yes	No	No
Palomba S et al. (2001) ⁵⁹	Other	70	Italy	2	Yes	No	Yes	Yes	Yes	No	No
Palomba S et al. (2002) ⁶⁰	Other	100	Italy	2	Yes	No	Yes	No	Yes	No	No
Palomba S et al. (2002) ⁶¹	NR	90	Italy	3	Yes	Yes	Yes	Yes	Yes	No	No
Palomba S et al. (2004) ⁶²	NA	100	Italy	2	Yes	No	No	No	Yes	No	No
Palomba S et al. (2007) ⁶³	NR	136	Italy	2	Yes	No	Yes	No	No	No	Yes
Palomba S et al. (2007) ⁶⁴	NA	136	Italy	2	Yes	No	No	No	No	No	Yes
Palomba S et al. (2008) ⁶⁵	Other	110	Italy	2	Yes	No	Yes	No	Yes	No	No
Parazzini F et al. (1999) ⁶⁶	Ind	72	Italy	2	Yes	No	Yes	No	Yes	No	Yes
Parsanezhad ME et al. (2010) ⁶⁷	Other	70	Multiple	2	Yes	No	Yes	No	Yes	No	No
Pinto I et al. (2003) ⁶⁸	NR	57	Spain	2	Yes	No	Yes	No	No	Yes	Yes
Rashid S et al. (2010) ⁶⁹	NA	157	Multiple	2	Yes	Yes	No	No	No	Yes	Yes
Rossetti A et al. (2001) ⁷⁰	NR	81	Italy	2	Yes	No	Yes	No	No	No	Yes
Ruuskanen A et al. (2010) ⁷¹	Multiple	57	Finland	2	Yes	No	Yes	No	No	Yes	Yes
Sadan O et al. (2001) ⁷²	NR	20	Israel	2	Yes	No	Yes	Yes	Yes	No	No
Sayyah-Melli M et al. (2009) ⁷³	Acad	60	Iran	2	Yes	No	Yes	No	Yes	No	No
Scialli AR et al. (1995) ⁷⁴	Ind	41	United States	2	Yes	No	Yes	No	Yes	No	No
Seracchioli R et al. (2000) ⁷⁵	NR	131	Italy	2	Yes	No	Yes	No	No	No	Yes
Seracchioli R et al. (2002) ⁷⁶	NR	122	Italy	2	Yes	No	Yes	No	No	No	Yes
Sesti F et al. (2008) ⁷⁷	Acad	80	Italy	2	Yes	No	Yes	No	No	No	Yes
Sesti F et al. (2008) ⁷⁸	Acad	100	Italy	2	Yes	No	Yes	No	No	No	Yes
Sesti F et al. (2014) ⁷⁹	NR	108	Italy	3	Yes	No	Yes	No	No	No	Yes
Shlansky-Goldberg RD et al. (2014) ⁸⁰	Ind	60	United States	2	Yes	No	Yes	No	No	Yes	No
Silva-Filho AL et al. (2006) ⁸¹	NR	60	Brazil	2	Yes	No	Yes	No	No	No	Yes
Simsek T et al. (2002) ⁸²	NR	46	Turkey	2	Yes	No	Yes	No	Yes	No	No
Siskin GP et al. (2008) ⁸³	NR	53	United States	2	Yes	No	Yes	No	No	Yes	No

Citation	Funding	Randomized	Country	Arms	KQ1	KQ2	Primary Study	Expectant Management	Medical	Procedural	Surgical
Song YG et al. (2013) ⁸⁴	NR	60	South Korea	2	Yes	No	Yes	No	No	Yes	No
Soriano D et al. (2001) ⁸⁵	NR	80	France	2	Yes	No	Yes	No	No	No	Yes
Soysal ME et al. (2001) ⁸⁶	NR	96	Turkey	2	Yes	No	Yes	No	No	No	Yes
Spies JB et al. (2004) ⁸⁷	NR	100	United States	2	Yes	No	Yes	No	No	Yes	No
Spies JB et al. (2005) ⁸⁸	NR	36	United States	2	Yes	No	Yes	No	No	Yes	No
Takeuchi H, Kobori H, Kikuchi I, et al. (2000) ⁸⁹	NR	67	Japan	2	Yes	No	Yes	No	Yes	No	No
Tan J et al. (2008) ⁹⁰	NA	52	China	2	Yes	No	Yes	No	No	No	Yes
Tan J et al. (2009) ⁹¹	NA	80	China	2	Yes	No	Yes	No	No	No	Yes
Tosun AK et al. (2014) ⁹²	NR	60	Turkey	2	Yes	No	Yes	No	Yes	No	No
van der Kooij SM et al. (2010) ⁹³	NA	177	Netherlands	2	Yes	Yes	No	No	No	Yes	Yes
van der Kooij SM et al. (2013) ⁹⁴	NA	177	Netherlands	2	Yes	No	No	No	No	Yes	Yes
Vercellino G et al. (2012) ⁹⁵	NR	166	Germany	2	Yes	No	Yes	No	No	No	Yes
Vilos GA et al. (2006) ⁹⁶	NR	26	Canada	2	Yes	No	Yes	No	No	Yes	No
Volkers NA et al. (2006) ⁹⁷	NA	177	Netherlands	2	Yes	Yes	No	No	No	Yes	Yes
Volkers NA et al. (2007) ⁹⁸	NA	177	Netherlands	2	Yes	No	No	No	No	Yes	Yes
Volkers NA et al. (2008) ⁹⁹	NA	177	Netherlands	2	Yes	No	No	No	No	Yes	Yes
Wang JJ et al. (2011) ¹⁰⁰	NR	384	China	2	Yes	No	Yes	No	No	No	Yes
Wang X et al. (2013) ¹⁰¹	Other	110	China	2	Yes	No	Yes	No	No	Yes	Yes
Wang X et al. (2013) ¹⁰²	NA	120	China	2	Yes	No	No	No	No	Yes	Yes
Watanabe Y et al. (1992) ¹⁰³	Govt	41	Japan	2	Yes	No	Yes	No	Yes	No	No
Worthington-Kirsch RL et al. (2011) ¹⁰⁴	Ind	46	United States	2	Yes	No	Yes	No	No	Yes	No
Yang Z et al. (2014) ¹⁰⁵	NR	40	China	2	Yes	No	Yes	No	No	Yes	No
Yen YK et al. (2001) ¹⁰⁶	NR	85	Taiwan	2	Yes	No	Yes	No	No	Yes	No
Yen YK et al. (2002) ¹⁰⁷	NR	61	Taiwan	2	Yes	No	Yes	No	No	No	Yes
Yu SC et al. (2011) ¹⁰⁸	NR	60	China	2	Yes	No	Yes	No	No	Yes	No
Zhao F et al. (2011) ¹⁰⁹	NR	105	China	3	Yes	No	Yes	No	No	No	Yes

Abbreviations: Ind = industry; Govt = government; NGO = non-government organization; Acad = academic; Oth = other; NR = not reported; NA = not applicable

Key Question 3

Studies included for Key Question 3 (n =14)

Citation	Design	Recruit Years	N	Procedure	Indication(s)
Raine-Bennett T, et al. (2016) ¹¹⁰	Population based cohort	2006-2013	34603	hysterectomy	leiomyoma
Zhang J, et al. (2016) ¹¹¹	Retrospective	2009-2013	3021	hysterectomy	presumed myoma; abnormal vaginal bleeding
Balgobin S, et al. (2016) ¹¹²	Retrospective	2006-2013	1629	hysterectomy	abnormal uterine bleeding, leiomyoma, pain, prolapse, stress urinary incontinence
Rodriguez AM, et al. (2015) ¹¹³	Retrospective	2002-2011	13964	hysterectomy; myomectomy	leiomyoma
Zhao WC, et al. (2015) ¹¹⁴	Retrospective	2008-2014	10248	hysterectomy; myomectomy	uterine fibroids
Picerno TM, et al. (2016) ¹¹⁵	Retrospective	2004-2015	1004	hysterectomy; myomectomy	NR
Brohl AS, et al. (2015) ¹¹⁶	Retrospective	1980-2014	2075	myomectomy	presumed benign leiomyoma
Tan-Kim J, et al. (2015) ¹¹⁷	Retrospective	2001-2012	3523	hysterectomy	NR
Cormio G, et al. (2015) ¹¹⁸	Retrospective	2000-2010	588	myomectomy	bleeding due to uterine fibroid
Zhang J, et al. (2015) ¹¹⁹	Retrospective	2009-2013	4248	myomectomy	menstrual disturbances, pelvic pain, myoma detection
Clark Donat L, et al. (2015) ¹²⁰	Retrospective	2011-2013	64	hysterectomy	leiomyoma
Bojahr B, et al. (2015) ¹²¹	Retrospective	1998-2014	10731	hysterectomy	symptomatic uterine myomas
Lieng M, et al. (2015) ¹²²	Retrospective	2000-2013	4791	hysterectomy, myomectomy	uterine fibroids
Brown J, et al. (2015) ¹²³	Retrospective	2002-2008	808	hysterectomy	menorrhagia; leiomyoma

Abbreviations: NR = not reported; N = number of individuals / patient records

Studies included for Key Question 3 (n = 133) from prior review

Citation	Design	Recruit	N	Age, Mean	Age, SD	LMS Rate
Adelusola KA, Ogunniyi SO (2001) ¹²⁴	Retrospective	ND	177	NR	NR	0/177
Ahmed AA, Stachurski J, Aziz EA, et al. (2002) ¹²⁵	Prospective	ND	10	NR	NR	0/10
Angle HS, Cohen SM, Hidlebaugh D (1995) ¹²⁶	Retrospective	ND	41	41	NR	0/41
Banaczek Z, Sikora K, Lewandowska-Andruszuk I (2004) ¹²⁷	Retrospective	ND	309	44.5	NR	0/309
Barbieri RL, Dilena M, Chumas J, et al. (1993) ¹²⁸	RCT	ND	20	33.7	NR	0/20
Begum S, Khan S (2004) ¹²⁹	Prospective	ND	91	NR	NR	0/91
Bernard JP, Rizk E, Camatte S, et al. (2001) ¹³⁰	Prospective	ND	75	NR	NR	0/75
Betjes HE, Hanstede MM, Emanuel MH, et al. (2009) ¹³¹	Retrospective	ND	539	44.3	NR	0/539

Citation	Design	Recruit	N	Age, Mean	Age, SD	LMS Rate
Birsan A, Deval B, Detchev R, et al. (2003) ¹³²	Prospective	ND	24	NR	NR	0/24
Bronz L, Suter T, Rusca T (1997) ¹³³	Prospective	ND	25	NR	NR	0/25
Butt JL, Jeffery ST, Van der Spuy ZM (2012) ¹³⁴	Retrospective	ND	106	NR	NR	0/106
Campo S, Campo V, Gambadauro P (2005) ¹³⁵	Prospective	ND	80	NR	NR	0/80
Chen SY, Chang DY, Sheu BC, et al. (2008) ¹³⁶	Prospective	ND	136	NR	NR	0/136
Cicinelli E, Romano F, Anastasio PS, et al. (1995) ¹³⁷	Prospective	ND	11	NR	NR	0/11
Colgan TJ, Pendergast S, LeBlanc M (1993) ¹³⁸	Retrospective	ND	77	36.9	NR	0/77
Corson SL, Brooks PG (1991) ¹³⁹	Retrospective	1986-1989	92	40.1	NR	2/92
Crescini C (1993) ¹⁴⁰	Prospective	ND	25	NR	NR	0/25
Dayoub N (2014) ¹⁴¹	Retrospective	ND	137	36	NR	0/137
De Falco M, Staibano S, Mascolo M, et al. (2009) ¹⁴²	RCT	ND	62	37.3	NR	0/62
Deligdisch L, Hirschmann S, Altchek A (1997) ¹⁴³	Retrospective	ND	60	NR	NR	0/60
Di Lieto A, De Falco M, Mansueto G, et al. (2005) ¹⁴⁴	RCT	ND	70	36.8	NR	0/70
Dijkhuizen FP, De Vries LD, Mol BW, et al. (2000) ¹⁴⁵	Prospective	ND	9	NR	NR	0/9
Dundr P, Mara M, Maskova J, et al. (2006) ¹⁴⁶	Retrospective	ND	20	NR	NR	0/20
El-Mowafi D, Madkour W, Lall C, et al. (2004) ¹⁴⁷	Retrospective	ND	165	45.8	NR	0/165
Emanuel MH, Wamsteker K (2005) ¹⁴⁸	Retrospective	ND	28	NR	NR	0/28
Emanuel MH, Wamsteker K, Hart AA, et al. (1999) ¹⁴⁹	Retrospective	1987-1995	285	NR	NR	1/285
Fanfani F, Fagotti A, Bifulco G, et al. (2005) ¹⁵⁰	Prospective	ND	213	NR	NR	0/213
Fedele L, Bianchi S, Dorta M, et al. (1991) ¹⁵¹	Prospective	ND	71	NR	NR	0/71
Ferrari MM, Berlanda N, Mezzopane R, et al. (2000) ²⁷	RCT	ND	62	NR	NR	0/62
Fukuda M, Shimizu T, Fukuda K, et al. (1993) ¹⁵²	Retrospective	ND	20	NR	NR	0/20
Garcia CR, Tureck RW (1984) ¹⁵³	Prospective	ND	17	NR	NR	0/17
Gavai M, Hupuczi P, Papp Z (2006) ¹⁵⁴	Retrospective	ND	504	33	NR	0/504
Gaym A (2004) ¹⁵⁵	Retrospective	ND	588	38.5	NR	0/588
Goldrath MH (1990) ¹⁵⁶	Retrospective	1982-1989	151	NR	NR	1/151
Gowri M, Mala G, Murthy S, et al. (2013) ¹⁵⁷	Retrospective	ND	259	NR	NR	0/259
Grigoriadis C, Papaconstantinou E, Mellou A, et al. (2012) ¹⁵⁸	Retrospective	ND	10	38.2	NR	0/10
Gurung G, Pradhan N, Rana SRA (2015) ¹⁵⁹	Retrospective	ND	40	NR	NR	0/40
Hallez JP (1995) ¹⁶⁰	Retrospective	ND	284	NR	NR	0/284
Hanafi M (2005) ¹⁶¹	Retrospective	ND	145	NR	NR	0/145
Hanafi M (2013) ¹⁶²	Retrospective	ND	134	43.7	NR	0/134
Harmanli OH, Bevilacqua SA, Dandolu V, et al. (2005) ¹⁶³	Retrospective	ND	333	44.2	NR	0/333
Hasson HM, Rotman C, Rana N, et al. (1992) ¹⁶⁴	Retrospective	ND	56	37.2	NR	0/56
Hasson HM, Rotman C, Rana N, et al. (1993) ¹⁶⁵	Retrospective	ND	22	40.4	NR	0/22
Hoffman MS, DeCesare S, Kalter C (1994) ¹⁶⁶	Prospective	ND	47	41.9	NR	0/47
Huang JQ, Lathi RB, Lemyre M, et al. (2010) ¹⁶⁷	Retrospective	ND	131	41	NR	0/131
Jansen FW, de Kroon CD, van Dongen H, et al. (2006) ¹⁶⁸	Prospective	ND	89	43.8	NR	0/89
Jha R, Pant AD, Jha A, et al. (2006) ¹⁶⁹	Retrospective	ND	55	37.6	NR	0/55

Citation	Design	Recruit	N	Age, Mean	Age, SD	LMS Rate
Johns DA, Diamond MP (1994) ¹⁷⁰	Retrospective	ND	11	39.2	NR	0/55
Kafy S, Huang JY, Al-Sunaidi M, et al. (2006) ¹⁷¹	Retrospective	ND	934	59.6	NR	0/934
Kalogiannidis I, Prapas N, Xiromeritis P, et al. (2010) ¹⁷²	Prospective	ND	75	34.8	4.5	0/75
Kamikabeya TS, Etchebehere RM, Nomelini RS, et al. (2010) ¹⁷³	Retrospective	1987-2008	1364	NR	NR	1/1364
Kiltz RJ, Rutgers J, Phillips J, et al. (1994) ¹⁷⁴	Prospective	ND	28	31	1.8	0/28
Kohama T, Hashimoto S, Ueno H, et al. (1997) ¹⁷⁵	Prospective	ND	25	NR	NR	0/25
Kuzel D, Toth D, Fucikova Z, et al. (1999) ¹⁷⁶	Prospective	ND	45	NR	NR	0/45
Landi S, Zaccoletti R, Ferrari L, et al. (2001) ¹⁷⁷	Prospective	ND	368	NR	NR	0/368
Laughead MK, Stones LM (1997) ¹⁷⁸	Prospective	ND	8	NR	NR	0/8
Leibsohn S, d'Ablaing G, Mishell DR, Jr., et al. (1990) ¹⁷⁹	Retrospective	1983-1988	1429	NR	NR	7/1429
Leung F, Terzibachian JJ, Gay C, et al. (2009) ¹⁸⁰	Retrospective	1996-2005	1297	48	NR	3/1297
Levens ED, Wesley R, Premkumar A, et al. (2009) ¹⁸¹	RCT	ND	18	NR	NR	0/18
Lim SS, Sockalingam JK, Tan PC (2008) ¹⁸²	RCT	ND	66	46.5	NR	0/66
Litta P, Fantinato S, Calonaci F, et al. (2010) ¹⁸³	RCT	ND	160	37.34	NR	0/160
Liu L, Li Y, Xu H, et al. (2011) ¹⁸⁴	Prospective	ND	167	NR	NR	0/167
Liu WM, Tzeng CR, Yi-Jen C, et al. (2004) ¹⁸⁵	Prospective	ND	486	NR	NR	0/486
Lyons TL, Adolph AJ, Winer WK (2004) ¹⁸⁶	Retrospective	ND	54	47.3	NR	0/54
MacKenzie IZ, Naish C, Rees M, et al. (2004) ¹⁸⁷	Retrospective	ND	118	47.5	NR	0/118
Mais V, Ajossa S, Guerriero S, et al. (1996) ⁴⁸	RCT	ND	40	NR	NR	0/40
Mansour FW, Kives S, Urbach DR, et al. (2012) ¹⁸⁸	Retrospective	ND	59	34.7	NR	0/59
Mara M, Fucikova Z, Kuzel D, et al. (2006) ¹⁸⁹	Prospective	ND	80	33.5	NR	0/80
Marana R, Busacca M, Zupi E, et al. (1999) ¹⁹⁰	RCT	ND	90	NR	NR	0/90
Mecke H, Wallas F, Brocker A, et al. (1995) ¹⁹¹	Retrospective	ND	215	36	NR	0/215
Mettler L, Alvarez-Rodas E, Semm K (1995) ¹⁹²	Retrospective	1990-1992	500	43.2	NR	1/500
Milad MP, Morrison K, Sokol A, et al. (2001) ¹⁹³	Prospective	ND	69	43.9	NR	0/69
Miskry T, Magos A (2003) ¹⁹⁴	RCT	ND	36	NR	NR	0/36
Modupeola S, Adesiyun A, Agunbiade O, et al. (2009) ¹⁹⁵	Retrospective	ND	196	44.6	NR	0/196
Moghadam R, Lathi RB, Shahmohamady B, et al. (2006) ¹⁹⁶	Retrospective	ND	144	41	NR	0/144
Muhammad Z, Ibrahim S, Agu O (2009) ¹⁹⁷	Retrospective	ND	78	46.6	NR	0/78
Munoz JL, Jimenez JS, Hernandez C, et al. (2003) ¹⁹⁸	Retrospective	ND	120	44.8	NR	0/120
Nezhat F, Nezhat CH, Admon D, et al. (1995) ¹⁹⁹	Retrospective	ND	28	NR	NR	0/28
Obed JY, Bako B, Usman JD, et al. (2011) ²⁰⁰	Prospective	ND	331	30.1	NR	0/331
O'Hanlan KA, Dibble SL, Garnier AC, et al. (2007) ²⁰¹	Retrospective	ND	258	50	NR	0/258
Okezie O, Ezegwui HU (2006) ²⁰²	Retrospective	ND	190	NR	NR	0/190
Ouldamer L, Rossard L, Arbion F, et al. (2014) ²⁰³	Retrospective	ND	709	49.5	NR	0/709
Palomba S, Orio F, Jr., Russo T, et al. (2005) ²⁰⁴	RCT	ND	40	53.4	NR	0/40
Palomba S, Zupi E, Falbo A, et al. (2010) ²⁰⁵	Prospective	ND	30	30.2	NR	0/30
Palomba S, Zupi E, Russo T, et al. (2007) ⁶⁴	RCT	ND	136	NR	NR	0/136
Parker WH, Fu YS, Berek JS (1994) ²⁰⁶	Retrospective	1988-1992	1332	NR	NR	1/1332

Citation	Design	Recruit	N	Age, Mean	Age, SD	LMS Rate
Paul GP, Naik SA, Madhu KN, et al. (2010) ²⁰⁷	Retrospective	1993-2009	1001	32.6	NR	1/1001
Perveen S, Tayyab S (2008) ²⁰⁸	Retrospective	ND	20	NR	NR	0/20
Phillips DR, Nathanson HG, Milim SJ, et al. (1995) ²⁰⁹	Prospective	ND	38	NR	NR	0/38
Polena V, Mergui JL, Perrot N, et al. (2007) ²¹⁰	Retrospective	ND	235	47.9	NR	0/235
Pron G, Mocarski E, Cohen M, et al. (2003) ²¹¹	Prospective	ND	8	NR	NR	0/8
Radosa MP, Owsianowski Z, Mothes A, et al. (2014) ²¹²	Retrospective	ND	221	37.9	NR	0/221
Rein MS, Friedman AJ, Stuart JM, et al. (1990) ²¹³	RCT	ND	20	NR	NR	0/20
Reiter RC, Wagner PL, Gambone JC (1992) ²¹⁴	Retrospective	ND	104	41.5	NR	0/104
Rosenblatt P, Makai G, DiSciullo A (2010) ²¹⁵	Retrospective	ND	24	50.2	NR	0/24
Rovio PH, Helin R, Heinonen PK (2009) ²¹⁶	Retrospective	ND	53	44.7	NR	0/53
Rutgers JL, Spong CY, Sinow R, et al. (1995) ²¹⁷	RCT	ND	22	38	NR	0/22
Sahagun Quevedo JA, Perez Ruiz JC, Cherem B, et al. (1994) ²¹⁸	Retrospective	ND	594	NR	NR	0/594
Sayyah-Melli M, Tehrani-Gadim S, Dastranj-Tabrizi A, et al. (2009) ⁷³	RCT	ND	23	39.67	NR	0/23
Schutz K, Possover M, Merker A, et al. (2002) ²¹⁹	RCT	ND	48	NR	NR	0/48
Seidman MA, Odusaye T, Muto MG, et al. (2012) ²²⁰	Retrospective	2005-2010	1091	NR	NR	1/1091
Seki K, Hoshihara T, Nagata I (1992) ²²¹	Retrospective	1979-1990	1886	45.5	NR	7/1886
Seracchioli R, Venturoli S, Vianello F, et al. (2002) ⁷⁶	RCT	ND	122	46.3	NR	0/122
Shen CC, Wu MP, Kung FT, et al. (2003) ²²²	Retrospective	ND	1521	45.5	NR	0/1521
Shergill SK, Shergill HK, Gupta M, et al. (2002) ²²³	RCT	ND	34	NR	NR	0/34
Sikora-Szcześniak DL, Sikora W, Szczęśniak G ²²⁴	Retrospective	ND	294	45.6	NR	0/294
Silva BA, Falcone T, Bradley L, et al. (2000) ²²⁵	Prospective	ND	39	37	NR	0/37
	Retrospective	ND	37	37	NR	0/37
Sinha R, Hegde A, Mahajan C, et al. (2008) ²²⁶	Prospective	1998-2005	505	34.44	NR	2/505
Takamizawa S, Minakami H, Usui R, et al. (1999) ²²⁷	Retrospective	1983-1997	923	44.5	NR	1/923
Tan J, Sun Y, Dai H, et al. (2008) ⁹⁰	RCT	ND	52	NR	NR	0/52
Tan J, Sun Y, Zhong B, et al. (2009) ⁹¹	RCT	ND	80	36.3	NR	0/80
Theben JU, Schellong AR, Altgassen C, et al. (2013) ²²⁸	Retrospective	1998-2005	1132	45.9	NR	2/1132
Tinelli A, Hurst BS, Hudelist G, et al. (2012) ²²⁹	Prospective	ND	235	NR	NR	0/235
Uccella S, Cromi A, Serati M, et al. (2014) ²³⁰	Retrospective	ND	71	48	NR	0/71
Ueki M, Okamoto Y, Tsurunaga T, et al. (1995) ²³¹	Retrospective	ND	230	42.5	NR	0/230
van Dongen H, Emanuel MH, Wolterbeek R, et al. (2008) ²³²	RCT	ND	22	48.2	NR	0/22
Vaniova Klimentova D, Braila AD, Simionescu C, et al. (2012) ²³³	Retrospective	ND	959	NR	NR	0/959
Varma R, Soneja H, Clark TJ, et al. (2009) ²³⁴	Prospective	2003-2006	92	NR	NR	1/92
Venkatesan AM, Partanen A, Pulanic TK, et al. (2012) ²³⁵	Prospective	ND	9	NR	NR	0/9
Walid MS, Heaton RL (2010) ²³⁶	Retrospective	ND	41	NR	NR	0/41
Wamsteker K, Emanuel MH, de Kruif JH (1993) ²³⁷	Prospective	ND	51	NR	NR	0/51
Wang CJ, Soong YK, Lee CL (2007) ²³⁸	Prospective	ND	18	NR	NR	0/18
West S, Ruiz R, Parker WH (2006) ²³⁹	Retrospective	ND	91	40	NR	0/91
Widrich T, Bradley LD, Mitchinson AR, et al.	Prospective	ND	6	NR	NR	0/6

Citation	Design	Recruit	N	Age, Mean	Age, SD	LMS Rate
(1996) ²⁴⁰						
Williams AR, Critchley HO, Osei J, et al. (2007) ²⁴¹	RCT	ND	33	NR	NR	0/33
Williams CD, Marshburn PB (1998) ²⁴²	Prospective	ND	5	38.5	NR	0/5
Wortman M, Daggett A (1995) ²⁴³	Retrospective	ND	75	43.2	NR	0/75
Yen YK, Liu WM, Yuan CC, et al. (2002) ¹⁰⁷	RCT	ND	64	NR	NR	0/64
Ylikorkala O, Tiitinen A, Hulkko S, et al. (1995) ²⁴⁴	RCT	ND	101	43	NR	0/101
Yoo EH, Lee PI, Huh CY, et al. (2007) ²⁴⁵	Retrospective	ND	512	33	NR	0/512
Yoon HJ, Kyung MS, Jung US, et al. (2007) ²⁴⁶	Retrospective	ND	51	34.9	NR	0/51
Zhu L, Lang JH, Liu CY, et al. (2009) ²⁴⁷	RCT	ND	101	NR	NR	0/101
Zullo F, Palomba S, Corea D, et al. (2004) ²⁴⁸	RCT	ND	60	28.2	NR	0/60

Abbreviations: ND = no data; NR = not reported; RCT = randomized controlled trial; SD = standard deviation; LMS = leiomyosarcoma;

Key Question 4

Studies included for Key Question 4 (n = 17)

Author	Design	Recruit Years	Country	N
Bojahr B et al., (2015) ¹²¹	Retrospective	1998-2014	Germany	10731
Einstein MH et al., (2008) ²⁴⁹	Retrospective	2000-2006	United States	NR
Graebe K et al., (2015) ²⁵⁰	Retrospective	2005-2013	United States	1361
Kamikabeya TS et al., (2010) ¹⁷³	Retrospective	1987-2008	Brazil	1364
Lieng M et al., (2015) ¹²²	Retrospective	2000-2013	Norway	4791
Lin KH et al., (2015) ²⁵¹	Retrospective	1993-2014	Taiwan	NR
Morice P et al., (2003) ²⁵²	Retrospective	1977-1997	Italy	123
Oduyebo T et al., (2014) ²⁵³	Prospective	2005-2012	United States	NR
Park JY et al., (2011) ²⁵⁴	Retrospective	1989-2010	South Korea	NR
Perri T et al., (2009) ²⁵⁵	Retrospective	1969-2005	United States	37
Seidman MA et al., (2012) ²²⁰	Retrospective	2005-2010	United States	1091
Sinha R et al., (2008) ²²⁶	Prospective	1998-2005	India	505
Takamizawa S et al., (1999) ²²⁷	Retrospective	1983-1997	Japan	923
Tan A et al., (2015) ²⁵⁶	Retrospective	2009-2015	Australia	734
Tan-Kim J et al., (2014) ²⁵⁷	Retrospective	2001-2012	United States	3523
Theben JU et al., (2013) ²²⁸	Retrospective	2005-2010	Germany	1584
Zhang J et al., (2015) ¹¹⁹	Retrospective	2009-2013	China	4248

Abbreviations: NR = not reported; N = number of individuals / patient records

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Appendix F. Risk of Bias Form and Summary

Risk of Bias Assessment Form: KQ1 Studies

Domain Domain-Specific Question	Response
Selection Bias (SB)	
SB1. Was the allocation sequence generated adequately (e.g., random number table, computer generated randomization)? Inadequate methods of allocation include non-random assignment (e.g., by participant last name, day of the week).	<ul style="list-style-type: none"> <input type="radio"/> Yes. The authors report an acceptable method of assigning participants to an intervention or control group. <input type="radio"/> No. The authors report an inadequate method of assignment to intervention or control group. <input type="radio"/> Not reported. The authors do not describe how participants were allocated to the intervention and control groups.
SB2. Was allocation adequately concealed (e.g., pharmacy-controlled, sealed envelopes)?	<ul style="list-style-type: none"> <input type="radio"/> Yes. The authors used an adequate method of allocation was concealed. <input type="radio"/> No. The authors did not use a method to conceal the allocation of participants to study arms or the allocation concealment was inadequate. <input type="radio"/> Not reported. Concealment is not described in the methods or mentioned by the publication authors.
SB3. Were the intervention and comparison groups comparable at baseline? Note: If randomization and allocation concealment approaches were successful, the groups should be similar.	<ul style="list-style-type: none"> <input type="radio"/> Yes. Baseline characteristics such as age, severity, and fibroid characteristics were similar between groups or differences between groups at baseline were minimal and likely due to chance. <input type="radio"/> No. There were differences between groups that may be a potential source of bias.
Overall assessment of selection bias:	<ul style="list-style-type: none"> <input type="radio"/> High <input type="radio"/> Medium <input type="radio"/> Low
Comments on sources of selection bias:	
Performance Bias (PB)	
PB1. Did authors describe allowable concurrent interventions or assess participants for use of concomitant interventions?	<ul style="list-style-type: none"> <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not reported
PB2. Did authors assess adherence (i.e., fidelity) to the intended treatment (e.g., collected pill counts, supplied and reviewed a medication diary), surgical, or procedural protocol?	<ul style="list-style-type: none"> <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not applicable

Domain	Response
Domain-Specific Question	
Overall assessment of performance bias:	<input type="radio"/> High <input type="radio"/> Medium <input type="radio"/> Low
Comments on sources of performance bias:	
Reporting Bias	
RB1. Were the outcomes specified a priori?	<input type="radio"/> Yes. Authors describe the outcomes and harms that would be assessed and reported. <input type="radio"/> No. Authors do not describe prespecified outcomes.
RB2. Were all prespecified outcomes reported in the findings/results?	<input type="radio"/> Yes. All prespecified outcomes were reported in the study publication. <input type="radio"/> No. One or more of the prespecified outcomes were not reported in the publication.
Overall assessment of reporting bias:	<input type="radio"/> High <input type="radio"/> Medium <input type="radio"/> Low
Comments on sources of reporting bias:	
Attrition Bias (AB)	
AB1. Did authors adequately report the disposition of all randomized participants?	<input type="radio"/> Yes. The authors described the number of participants who were analyzed and accounted for participants who were lost to follow-up and/or dropped out. <input type="radio"/> No. The authors did not account for participants who did not complete the study.
Mark "yes" if there was no attrition (i.e., the number randomized equals the number reported in followup).	
Intervention LTF rate:	
Control LTF rate:	
Study LTF rate:	
AB2. Were characteristics of the lost-to-followup / drop-out group evaluated for differences with the study group?	<input type="radio"/> Yes. Authors compare the loss-to-followup / drop-outs group to the whole group. <input type="radio"/> No. Authors do not comment on the characteristics of the group lost to followup compared with the overall study population. <input type="radio"/> Not applicable. Attrition was minimal or none.
AB3. Did authors use an intention-to-treat approach in analysis of outcomes?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not reported
AB4. Were incomplete outcome data adequately	<input type="radio"/> Yes. Authors used an appropriate method for missing data (e.g., imputation), the missing data was minimal

Domain Domain-Specific Question	Response
addressed?	<p>and reasons were similar between groups, or there was no missing data.</p> <ul style="list-style-type: none"> <input type="radio"/> No. Authors did not address missing data, a substantial proportion of patients withdrew, or missing outcome data could have biased observed effect size. <input type="radio"/> Not sure.
How did authors handle missing data?	
Overall assessment of attrition bias:	<ul style="list-style-type: none"> <input type="radio"/> High <input type="radio"/> Medium <input type="radio"/> Low
Comments on sources of attrition bias:	
Detection Bias (DB)	
DB1. Was the intervention fully described?	<ul style="list-style-type: none"> <input type="radio"/> Yes. The authors reported sufficient detail to allow replication of the intervention or the authors reference a treatment manual. <input type="radio"/> No. The authors did not report sufficient detail to replicate the intervention.
DB2. Was the length of followup similar for all study groups for primary outcomes?	<ul style="list-style-type: none"> <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not reported
DB3. Were the primary outcomes coded by individuals blinded to the intervention status of the participants?	<ul style="list-style-type: none"> <input type="radio"/> Yes. The outcome assessors were unaware of an individual participant's group assignment. <input type="radio"/> No. The outcome assessors knew which group participants were assigned to. <input type="radio"/> Not reported
DB4. Did authors use reliable and valid measures/tools to assess primary outcomes?	<ul style="list-style-type: none"> <input type="radio"/> Yes. Outcomes were assessed using previously validated measure(s) or the authors establish the validity in the current publication. <input type="radio"/> No. The outcomes were assessed using measures of uncertain validity and reliability. <input type="radio"/> Not sure. There is not enough information to rate this criterion.
Overall assessment of detection bias:	<ul style="list-style-type: none"> <input type="radio"/> High <input type="radio"/> Medium <input type="radio"/> Low
Comments on sources of detection bias:	
Other Bias (OB)	
OB1. Was a priori sample size calculation provided for the primary outcome?	<ul style="list-style-type: none"> <input type="radio"/> Yes <input type="radio"/> No

Domain Domain-Specific Question	Response
See http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3409926/ for more information on estimating sample size for clinical studies.	
Overall assessment of other bias:	<input type="radio"/> High <input type="radio"/> Medium <input type="radio"/> Low
Comments on sources of other bias:	
Risk of Bias for Individual Outcomes	
Risk of bias associated with specific outcome(s) of interest differs from the risk of bias assessments above?	<input type="radio"/> Yes (or likely yes) <input type="radio"/> No <input type="radio"/> Unsure
Assess risk of bias for harm(s) reported in this study?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure

Assessment of Overall Risk of Bias for Individual Studies

The team preselected individual questions to assess the risk of bias in randomized controlled trials from a list of design-specific criteria.¹ The team developed an appraisal form that included 16 questions across six domains:

- Selection Bias (*3 items*)
- Performance bias (*2 items*)
- Reporting bias (*2 items*)
- Attrition bias (*4 items*)
- Detection bias (*4 item*)
- Other bias (*1 item*)

Two team members independently assessed the risk of bias for each domain. Conflicts were reconciled through discussion.

We used the cumulative assessments from the six domains to categorize studies as high risk of bias, medium risk of bias, or low risk of bias based on the following:

- Low risk of bias: low risk of bias for all domains OR low risk of bias in all domains except for masking of those conducting imaging when placebo was used or the individual conducting the original intervention was not involved in the imaging.
- Medium risk of bias: medium risk of bias for one or two domains OR unclear risk of bias for one or more domains, together with no known important limitation that could invalidate its results.
- High risk of bias: medium risk of bias for 3 or more domains OR high risk of in any domain

The overall risk of bias for the study was calculated from individual domain assessments:

- Low risk of bias = **Good** quality
- Medium risk of bias = **Fair** quality
- High risk of bias = **Poor** quality

Risk of Bias Assessment Summary: KQ1 RCTs

Citation	Participants	Selection	Performance	Reporting	Attrition	Detection	Other	Low Count	Medium Count	High Count	Overall Low	Overall Medium	Overall High
Alessandri F et al. (2006) ²	148	L	L	L	H	M	M	3	2	1			●
Ardovino M et al. (2013) ³	170	M	H	L	M	M	M	1	4	1			●
Benassi L et al. (2002) ⁴	119	L	L	L	L	M	L	5	1	0	●		
Bilhim T et al. (2011) ⁵	160	M	M	M	M	M	H	0	5	1			●
Broekmans FJ et al. (1996) ⁶	27	H	H	L	H	M	H	1	1	4			●
Brucker SY et al. (2014) ⁷	51	M	L	H	M	M	M	1	4	1			●
Carbonell Esteve JL et al. (2008) ⁸	100	M	M	L	L	L	L	4	2	0	●		
Carbonell JL et al. (2013) ⁹	220	M	L	L	H	M	L	3	2	1			●
Carbonell JL et al. (2013) ¹⁰	70	L	L	L	M	L	L	5	1	0	●		
Carr BR et al. (1993) ¹¹	16	H	H	L	L	L	H	3	0	3			●
Casini ML et al. (2006) ¹²	181	H	H	L	M	M	H	1	2	3			●
Chwalisz K et al. (2007) ¹³	129	L	L	L	L	M	L	5	1	0	●		
Cicinelli E et al. (2009) ¹⁴	80	M	M	L	L	M	H	2	3	1			●
Costantini S et al. (1990) ¹⁵	42	H	H	L	L	L	H	3	0	3			●
Cunningham E et al. (2008) ¹⁶	16	L	L	L	H	L	M	4	1	1			●
Donnez J et al. (2015) ¹⁷	451	L	M	L	L	L	L	5	1	0	●		
Edwards RD et al. (2007) ¹⁸	157	L	L	L	M	L	L	5	1	0	●		
Eisinger SH et al. (2003) ¹⁹	40	L	M	L	L	M	L	4	2	0	●		
Esteve JL et al. (2012) ²⁰	176	L	L	L	M	L	L	5	1	0	●		
Esteve JL et al. (2013) ²¹	124	M	M	L	H	L	L	3	2	1			●
Fedele L et al. (1991) ²²	42	M	M	L	M	M	M	1	5	0			●
Fedele L et al. (2000) ²³	38	M	M	L	L	M	M	2	4	0			●
Ferrari MM et al. (2000) ²⁴	62	L	L	L	L	L	M	5	1	0	●		
Fiscella K et al. (2006) ²⁵	42	M	L	L	L	L	L	5	1	0	●		
Friedman AJ et al. (1988) ²⁶	16	H	M	L	L	M	M	2	3	1			●

Citation	Participants	Selection	Performance	Reporting	Attrition	Detection	Other	Low Count	Medium Count	High Count	Overall Low	Overall Medium	Overall High
Friedman AJ et al. (1989) ²⁷	38	M	L	L	L	M	4	2	0		•		
Friedman AJ et al. (1991) ²⁸	128	M	L	L	H	M	M	2	3	1		•	
Friedman AJ et al. (1993) ²⁹	51	H	H	L	H	M	H	1	1	4		•	
Gregoriou O et al. (1997) ³⁰	40	H	H	L	L	M	H	2	1	3		•	
Hald K et al. (2007) ³¹	66	L	L	L	M	L	L	5	1	0	•		
Hehenkamp WJ et al. (2005) ³²	177	L	L	L	L	L	L	6	0	0	•		
Hwang JL et al. (2002) ³³	90	L	L	L	L	M	L	5	1	0	•		
Jiang N et al. (2014) ³⁴	80	H	M	L	L	M	H	2	2	2		•	
Jirecek S et al. (2004) ³⁵	25	M	M	L	M	M	M	1	5	0		•	
Jun F et al. (2012) ³⁶	127	M	L	L	L	M	M	3	3	0		•	
Levens E et al. (2008) ³⁷	22	L	M	L	M	L	H	3	2	1		•	
Liu M et al. (2011) ³⁸	359	M	M	L	M	L	L	3	3	0		•	
Mais V et al. (1996) ³⁹	40	L	L	L	L	M	M	4	2	0	•		
Manyonda IT et al. (2012) ⁴⁰	163	L	L	L	M	L	L	5	1	0	•		
Mara M et al. (2006) ⁴¹	63	L	L	L	L	M	M	4	2	0	•		
Melli MS et al. (2007) ⁴²	50	M	M	L	M	H	M	1	4	1		•	
Meng X et al. (2010) ⁴³	100	H	M	L	M	M	H	1	3	2		•	
Morris EP et al. (2008) ⁴⁴	75	M	M	L	M	L	L	3	3	0		•	
Nieman LK et al. (2011) ⁴⁵	42	L	M	L	L	L	H	4	1	1		•	
Orsi F et al. (2015) ⁴⁶	33	M	M	L	M	M	H	1	4	1		•	
Palomba S et al. (1998) ⁴⁷	50	M	M	L	L	L	L	4	2	0	•		
Palomba S et al. (2001) ⁴⁸	70	L	M	L	M	L	L	4	2	0	•		
Palomba S et al. (2002) ⁴⁹	100	L	L	L	L	M	L	5	1	0	•		
Palomba S et al. (2002) ⁵⁰	90	L	L	L	M	L	L	5	1	0	•		
Palomba S et al. (2007) ⁵¹	136	L	L	L	L	L	M	5	1	0	•		
Palomba S et al. (2008) ⁵²	110	L	M	L	L	M	H	3	2	1		•	
Parazzini F et al. (1999) ⁵³	72	H	M	L	H	M	M	1	3	2		•	
Parsanezhad ME et al. (2010) ⁵⁴	70	M	M	L	M	L	H	2	3	1		•	
Pinto I et al. (2003) ⁵⁵	57	M	L	L	M	L	L	4	2	0	•		
Rossetti A et al. (2001) ⁵⁶	81	L	L	L	L	L	M	5	1	0	•		

Citation	Participants	Selection	Performance	Reporting	Attrition	Detection	Other	Low Count	Medium Count	High Count	Overall Low	Overall Medium	Overall High
Ruuskanen A et al. (2010) ⁵⁷	57	M	L	L	L	M	H	3	2	1			●
Sadan O et al. (2001) ⁵⁸	20	M	M	L	L	M	M	2	4	0			●
Sayyah-Melli M et al. (2009) ⁵⁹	60	M	M	L	H	M	H	1	3	2			●
Scialli AR et al. (1995) ⁶⁰	41	M	M	L	M	H	M	1	4	1			●
Seracchioli R et al. (2000) ⁶¹	131	L	L	L	M	M	L	4	2	0		●	
Seracchioli R et al. (2002) ⁶²	122	L	L	L	L	M	H	4	1	1			●
Sesti F et al. (2008) ⁶³	80	L	L	L	L	L	L	6	0	0	●		
Sesti F et al. (2008) ⁶⁴	100	L	L	L	L	L	L	6	0	0	●		
Sesti F et al. (2014) ⁶⁵	108	L	L	L	L	L	L	6	0	0	●		
Shlansky-Goldberg RD et al. (2014) ⁶⁶	60	L	L	L	L	L	L	6	0	0	●		
Silva-Filho AL et al. (2006) ⁶⁷	60	M	M	L	L	L	H	3	2	1			●
Simsek T et al. (2002) ⁶⁸	46	H	M	H	H	M	H	0	2	4			●
Siskin GP et al. (2008) ⁶⁹	53	L	L	L	L	L	L	6	0	0	●		
Song YG et al. (2013) ⁷⁰	60	M	L	L	L	M	L	4	2	0		●	
Soriano D et al. (2001) ⁷¹	80	M	L	L	L	L	M	4	2	0		●	
Soysal ME et al. (2001) ⁷²	96	L	L	L	L	L	M	5	1	0		●	
Spies JB et al. (2004) ⁷³	100	L	L	L	M	M	L	4	2	0		●	
Spies JB et al. (2005) ⁷⁴	36	L	L	L	L	L	L	6	0	0	●		
Takeuchi H, Kobori H, Kikuchi I, et al. (2000) ⁷⁵	67	H	L	L	H	M	H	2	1	3			●
Tan J et al. (2008) ⁷⁶	52	L	L	L	L	M	L	5	1	0	●		
Tan J et al. (2009) ⁷⁷	80	L	L	L	L	L	L	6	0	0	●		
Tosun AK et al. (2014) ⁷⁸	60	H	H	M	H	M	H	0	2	4			●
Vercellino G et al. (2012) ⁷⁹	166	L	H	L	M	M	L	3	2	1			●
Vilos GA et al. (2006) ⁸⁰	26	L	L	L	H	L	H	4	0	2			●
Wang JJ et al. (2011) ⁸¹	384	L	L	L	L	L	L	6	0	0	●		
Wang X et al. (2013) ⁸²	110	M	L	L	M	L	M	3	3	0			●
Watanabe Y et al. (1992) ⁸³	41	M	M	L	M	M	H	1	4	1			●
Worthington-Kirsch RL et al. (2011) ⁸⁴	46	M	L	L	M	L	L	4	2	0		●	
Yang Z et al. (2014) ⁸⁵	40	M	M	L	M	M	L	2	4	0			●

Citation	Participants	Selection	Performance	Reporting	Attrition	Detection	Other	Low Count	Medium Count	High Count	Overall Low	Overall Medium	Overall High
Yen YK et al. (2001) ⁸⁶	81	H	L	L	M	M	M	2	3	1			●
Yen YK et al. (2002) ⁸⁷	61	H	L	L	M	M	M	2	3	1			●
Yu SC et al. (2011) ⁸⁸	60	L	L	L	L	L	L	6	0	0	●		
Zhao F et al. (2011) ⁸⁹	105	H	M	L	M	M	M	1	4	1			●

Abbreviations: L=low; M=medium; H=high; N=number of participants.

Overall Risk of Bias	Citation	Risk of Bias Assessment												Participants
		Selection	Performance	Reporting	Attrition	Detection	Other	Low Count	Medium Count	High Count	Overall Low	Overall Medium	Overall High	
Low (15 Studies; 1,628)	Benassi L et al. (2002) ⁴	L	L	L	L	M	L							119
	Chwalisz K et al. (2007) ¹³	L	L	L	L	M	L							129
	Hehenkamp WJ et al. (2005) ³²	L	L	L	L	L	L							177
	Hwang JL et al. (2002) ³³	L	L	L	L	M	L							90
	Palomba S et al. (2002) ⁴⁹	L	L	L	L	M	L							100
	Sesti F et al. (2008) ⁶³	L	L	L	L	L	L							80
	Sesti F et al. (2008) ⁶⁴	L	L	L	L	L	L							100
	Sesti F et al. (2014) ⁶⁵	L	L	L	L	L	L							108
	Shlansky-Goldberg RD et al. (2014) ⁶⁶	L	L	L	L	L	L							60
	Siskin GP et al. (2008) ⁶⁹	L	L	L	L	L	L							53
	Spies JB et al. (2005) ⁷⁴	L	L	L	L	L	L							36
	Tan J et al. (2008) ⁷⁶	L	L	L	L	M	L							52
	Tan J et al. (2009) ⁷⁷	L	L	L	L	L	L							80
	Wang JJ et al. (2011) ⁸¹	L	L	L	L	L	L							384
	Yu SC et al. (2011) ⁸⁸	L	L	L	L	L	L							60
Medium (25 Studies; 2,465)	Carbonell Esteve JL et al. (2008) ⁸	M	M	L	L	L	L							100
	Carbonell JL et al. (2013) ¹⁰	L	L	L	M	L	L							70
	Donnez J et al. (2015) ¹⁷	L	M	L	L	L	L							451
	Edwards RD et al. (2007) ¹⁸	L	L	L	M	L	L							157
	Eisinger SH et al. (2003) ¹⁹	L	M	L	L	M	L							40
	Esteve JL et al. (2012) ²⁰	L	L	L	M	L	L							176
	Ferrari MM et al. (2000) ²⁴	L	L	L	L	L	M							62
	Fiscella K et al. (2006) ²⁵	M	L	L	L	L	L							42
	Friedman AJ et al. (1989) ²⁷	M	L	L	L	L	M							38
	Hald K et al. (2007) ³¹	L	L	L	M	L	L							66
	Mais V et al. (1996) ³⁹	L	L	L	L	M	M							40

Overall Risk of Bias	Citation	Selection	Performance	Reporting	Attrition	Detection	Other	Participants
High (47 Studies, 3,806)	Manyonda IT et al. (2012) ⁴⁰	L	L	L	M	L	L	163
	Mara M et al. (2006) ⁴¹	L	L	L	L	M	M	63
	Palomba S et al. (1998) ⁴⁷	M	M	L	L	L	L	50
	Palomba S et al. (2001) ⁴⁸	L	M	L	M	L	L	70
	Palomba S et al. (2002) ⁵⁰	L	L	L	M	L	L	90
	Palomba S et al. (2007) ⁵¹	L	L	L	L	L	M	136
	Pinto I et al. (2003) ⁵⁵	M	L	L	M	L	L	57
	Rossetti A et al. (2001) ⁵⁶	L	L	L	L	L	M	81
	Seracchioli R et al. (2000) ⁶¹	L	L	L	M	M	L	131
	Song YG et al. (2013) ⁷⁰	M	L	L	L	M	L	60
	Soriano D et al. (2001) ⁷¹	M	L	L	L	L	M	80
	Soysal ME et al. (2001) ⁷²	L	L	L	L	L	M	96
	Spies JB et al. (2004) ⁷³	L	L	L	M	M	L	100
	Worthington-Kirsch RL et al. (2011) ⁸⁴	M	L	L	M	L	L	46
	Alessandri F et al. (2006) ²	L	L	L	H	M	M	148
	Ardovino M et al. (2013) ³	M	H	L	M	M	M	170
	Bilhim T et al. (2011) ⁵	M	M	M	M	M	H	160
	Broekmans FJ et al. (1996) ⁶	H	H	L	H	M	H	27
	Brucker SY et al. (2014) ⁷	M	L	H	M	M	M	51
	Carbonell JL et al. (2013) ⁹	M	L	L	H	M	L	220
	Carr BR et al. (1993) ¹¹	H	H	L	L	L	H	16
	Casini ML et al. (2006) ¹²	H	H	L	M	M	H	181
	Cicinelli E et al. (2009) ¹⁴	M	M	L	L	M	H	80
	Costantini S et al. (1990) ¹⁵	H	H	L	L	L	H	42
	Cunningham E et al. (2008) ¹⁶	L	L	L	H	L	M	16
	Esteve JL et al. (2013) ²¹	M	M	L	H	L	L	124
	Fedele L et al. (1991) ²²	M	M	L	M	M	M	42
	Fedele L et al. (2000) ²³	M	M	L	L	M	M	38
	Friedman AJ et al. (1988) ²⁶	H	M	L	L	M	M	16
	Friedman AJ et al. (1991) ²⁸	M	L	L	H	M	M	128
	Friedman AJ et al. (1993) ²⁹	H	H	L	H	M	H	51
	Gregoriou O et al. (1997) ³⁰	H	H	L	L	M	H	40
	Jiang N et al. (2014) ³⁴	H	M	L	L	M	H	80
	Jirecek S et al. (2004) ³⁵	M	M	L	M	M	M	25
	Jun F et al. (2012) ³⁶	M	L	L	L	M	M	127
	Levens E et al. (2008) ³⁷	L	M	L	M	L	H	22
	Liu M et al. (2011) ³⁸	M	M	L	M	L	L	359
	Melli MS et al. (2007) ⁴²	M	M	L	M	H	M	50
	Meng X et al. (2010) ⁴³	H	M	L	M	M	H	100
	Morris EP et al. (2008) ⁴⁴	M	M	L	M	L	L	75

Overall Risk of Bias	Citation	Selection	Performance	Reporting	Attrition	Detection	Other	Participants
	Nieman LK et al. (2011) ⁴⁵	L	M	L	L	L	H	42
	Orsi F et al. (2015) ⁴⁶	M	M	L	M	M	H	33
	Palomba S et al. (2008) ⁵²	L	M	L	L	M	H	110
	Parazzini F et al. (1999) ⁵³	H	M	L	H	M	M	72
	Parsanezhad ME et al. (2010) ⁵⁴	M	M	L	M	L	H	70
	Ruuskanen A et al. (2010) ⁵⁷	M	L	L	L	M	H	57
	Sadan O et al. (2001) ⁵⁸	M	M	L	L	M	M	20
	Sayyah-Melli M et al. (2009) ⁵⁹	M	M	L	H	M	H	60
	Scialli AR et al. (1995) ⁶⁰	M	M	L	M	H	M	41
	Seracchioli R et al. (2002) ⁶²	L	L	L	L	M	H	122
	Silva-Filho AL et al. (2006) ⁶⁷	M	M	L	L	L	H	60
	Simsek T et al. (2002) ⁶⁸	H	M	H	H	M	H	46
	Takeuchi H, Kobori H, Kikuchi I, et al. (2000) ⁷⁵	H	L	L	H	M	H	67
	Tosun AK et al. (2014) ⁷⁸	H	H	M	H	M	H	60
	Vercellino G et al. (2012) ⁷⁹	L	H	L	M	M	L	166
	Vilos GA et al. (2006) ⁸⁰	L	L	L	H	L	H	26
	Wang X et al. (2013) ⁸²	M	L	L	M	L	M	110
	Watanabe Y et al. (1992) ⁸³	M	M	L	M	M	H	41
	Yang Z et al. (2014) ⁸⁵	M	M	L	M	M	L	40
	Yen YK et al. (2001) ⁸⁶	H	L	L	M	M	M	81
	Yen YK et al. (2002) ⁸⁷	H	L	L	M	M	M	61
	Zhao F et al. (2011) ⁸⁹	H	M	L	M	M	M	105

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Appendix G. Registered Study Protocols

Registered protocols from studies included in Key Question 1

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
PGL4001 Efficacy Assessment in Reduction of Symptoms Due to Uterine Leiomyomata NCT01629563 (See Ref ID: 95)	Drug: PGL4001 5 mg Drug: PGL4001 10 mg	PregLem SA Industry	6/1/2012; 1/1/2015 Completed, No Results Available	551
A Study to Evaluate the Safety and Effectiveness of Asoprisnil in the Treatment of Uterine Fibroids NCT00160459 (See Ref ID: 3324)	Drug: Asoprisnil	Abbott Industry	5/1/2000; 7/1/2001 Completed, No Results Available	129
Mifepristone to Treat Uterine Fibroids NCT01786226 (See Ref ID: 629)	Drug: Oral administration of mifepristone 2.5 mg daily for three months Drug: Oral administration of mifepristone 5 mg daily for three months	Mediterranea Medica S. L. Other	3/1/2010; 3/1/2012 Terminated, No Results Available	220
PGL4001 Efficacy Assessment in Reduction of Symptoms Due to Uterine Leiomyomata NCT01156857 (See Ref ID: 414)	Drug: PGL4001, placebo Drug: PGL4001, progestin	PregLem SA Industry	7/1/2010; 2/1/2012 Completed, No Results Available	209
PGL4001 Efficacy Assessment in Reduction of Symptoms Due to Uterine Leiomyomata (PEARLIII-extension Study) NCT01252069 (See Ref ID: 414)	Drug: PGL4001, placebo, drug free period Drug: PGL4001, progestin, drug free period	PregLem SA Industry	1/1/2011; 1/1/2014 Completed, No Results Available	200

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Mifepristone 10 or 5 mg for 6 Months to Treat Uterine Fibroids NCT00886873 (See Ref ID: 2635)	Drug: Mifepristone	Mediterranea Medica S. L. Other	5/1/2008; 5/1/2009 Completed, No Results Available	100
Treatment of Uterine Fibroids With the Selective Progesterone Receptor Modulator CDB-2914 NCT00290251 (See Ref ID: 1849)	Drug: Ulipristal acetate Drug: Ulipristal acetate Drug: Placebo	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) HRA Pharma National Institutes of Health Clinical Center (CC) NIH, Industry	2/1/2006; 8/1/2010 Completed, Has Results	72
Trial of Mifepristone for Fibroids NCT00133705 (See Ref ID: 3407)	Drug: Mifepristone	University of Rochester Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Other, NIH	7/1/2003; 6/1/2010 Completed, Has Results	70
High Intensity Focused Ultrasound Ablation Virus Myomectomy to Treat Uterine Fibroids NCT01239641 (See Ref ID: 793; 804)	Procedure: High intensity focused ultrasound	Chongqing Medical University Other	9/1/2010; 7/1/2013 Recruiting, No Results Available	220

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Emmy Trial: Uterine Artery Embolization (UAE) Versus Hysterectomy for Uterine Fibroids NCT00100191 (See Ref ID: 815; 1986; 2759; 2971; 3120; 3175; 3192; 3678; 3721; 3819)	Procedure: Embolization Procedure: Hysterectomy	The Netherlands Organisation for Health Research and Development Boston Scientific Corporation Other, Industry	2/1/2002; 4/1/2006 Completed, No Results Available	120
A Prospective Study Comparing Contour SE™ Microspheres to Embosphere® Microspheres for Treating Symptomatic Uterine Fibroids With Uterine Fibroid Embolization (UFE) NCT00628901 (See Ref ID: 347)	Procedure: Embolization Device: Contour SE™ Microspheres Device: Embosphere® Microspheres	Boston Scientific Corporation Industry	1/1/2006; 1/1/2011 Completed, Has Results	60
Laparoscopic Uterine Sparing Techniques Outcomes and Reinterventions NCT01750008 (See Ref ID: 392)	Procedure: Global Fibroid Ablation Procedure: Myomectomy	Halt Medical, Inc. Industry	11/1/2012; 9/1/2018 Active, Not Recruiting, No Results Available	50
Comparison Study in the Treatment of Uterine Fibroids Uterine Fibroid Embolization Using BeadBlock™ Embolic Agent NCT00361036 (See Ref ID: 1806)	Device: Uterine fibroid embolization BeadBlock™ Device: Uterine fibroid embolization Embosphere®	Worthington-Kirsch, Robert L., M.D. Terumo Medical Corporation Biocompatibles UK Ltd Other, Industry	8/1/2006; 3/1/2010 Completed, No Results Available	44
Laparoscopic Occlusion of Uterine Vessels Compared to Uterine Fibroid Embolization for Treatment of Uterine	Procedure: Laparoscopic bilateral occlusion of uterine artery	Ullevaal University Hospital	12/1/2000; 4/1/2010	60

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Fibroids NCT00277680 (See Ref ID: 2303; 3382)	Procedure: Radiological embolization (UFE)	Oslo University Hospital Other	Active, Not Recruiting, No Results Available	
Temporary Clipping of the Uterine Arteries During Laparoscopic Myomectomy NCT01530802 (See Ref ID: 1108)	Procedure: Clipping of uterine arteries during laparoscopic myomectomy	Charite University, Berlin, Germany Other	1/1/2007; 12/1/2009 Completed, No Results Available	166
Multicentre randomised controlled trial comparing uterine artery embolisation with surgical treatment for uterine fibroids ISRCTN23023665 (See Ref ID: 3365)	Procedure: Embolisation Procedure: Surgery	Greater Glasgow Health Board (North Glasgow University Hospitals Division) (UK) Government	1/11/2000; 1/09/2010 Completed, No Results Available	200

Registered protocols for ongoing studies of interventions for uterine fibroids

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Evaluation of a Hysteroscopic Morcellator in Hysteroscopic Treatment of Submucosal Fibroids NCT02406898	Device: Morcellator uterine system (MH) Karl Storz, Tuttlingen-Germany	Assistance Publique Hopitaux De Marseille Other	4/1/2015; 3/1/2018 Not Yet Recruiting, No Results Available	60
Safety and Efficacy in Premenopausal Women With Heavy Menstrual Bleeding (HMB) Associated With Uterine Fibroids (UF) NCT01817530	Drug: Elagolix, elagolix sodium	AbbVie Industry	1/1/2013; 12/1/2015 Active, Not Recruiting, No Results Available	520
A Study of the Safety and Efficacy of Intermittent	Drug: Ulipristal acetate (UPA) 5	Watson	1/1/2014; 12/1/2015	400

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Ulipristal Treatment of Abnormal Uterine Bleeding Associated With Leiomyomas NCT02147158	mg Drug: Ulipristal acetate (UPA) 10 mg Drug: Placebo	Pharmaceuticals Industry	Recruiting, No Results Available	
Bay1002670, Fibroids, Safety and Efficacy NCT02131662	 Drug: BAY1002670	Bayer Industry	5/1/2014; 3/1/2016 Recruiting, No Results Available	300
Ulipristal Acetate 10 mg and Assisted Reproduction NCT02425878	 Drug: Ulipristal Acetate Drug: Placebo	Instituto Valenciano de Infertilidad, IVI VALENCIA Other	5/1/2015; Null Not Yet Recruiting, No Results Available	282
Safety and Efficacy Pre-Menopausal Women With Heavy Uterine Bleeding and Uterine Fibroids NCT01441635	 Drug: Elagolix, elagolix sodium	AbbVie Industry	9/1/2011; 2/1/2014 Completed, No Results Available	271
A Study of the Efficacy and Safety of a Single Ulipristal Treatment Course for the Treatment of Abnormal Uterine Bleeding Associated With Leiomyomas NCT02147197	 Drug: Ulipristal acetate 5 mg Drug: Ulipristal acetate 10 mg Drug: Placebo	Watson Pharmaceuticals Industry	4/1/2014; 3/1/2015 Recruiting, No Results Available	150
Ulipristal Acetate Versus GnRH Analogue Treatment Before Hysteroscopic Resection of Uterine Leiomyoma NCT02361879	 Drug: Ulipristal acetate Drug: Leuprolide acetate	University Magna Graecia Other	2/1/2015; 9/1/2017 Recruiting, No Results Available	146

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Ulipristal Acetate Versus GnRH Analogue and Myometrial Preservation NCT02357563	Drug: Ulipristal acetate Drug: Leuprolide acetate	University Magna Graecia Other	2/1/2015; 9/1/2017 Recruiting, No Results Available	110
Ulipristal vs. GnRHa Prior to Laparoscopic Myomectomy NCT02288130	Drug: GnRHa Drug: Ulipristal	VU University Medical Center Other	12/1/2014; 9/1/2016 Recruiting, No Results Available	100
PGL4001 Efficacy Assessment in Reduction of Symptoms Due to Uterine Leiomyomata NCT01642472	Drug: Ulipristal acetate - open label	PregLem SA Industry	7/1/2012; 11/1/2014 Active, Not Recruiting, No Results Available	90
Study of Tumor-shrinking Decoction (TSD) to Treat Symptomatic Uterine Fibroids NCT02189083	Drug: TSD	The University of Hong Kong Other	5/1/2014; 2/1/2016 Recruiting, No Results Available	78
The Effect of Ulipristal Acetate (UPA) on Women Ovarian Reserve NCT02361892	Drug: Ulipristal acetate	University Magna Graecia Other	2/1/2015; 9/1/2017 Recruiting, No Results Available	73
Study of the Efficacy of Dienogest in the Treatment of Uterine Leiomyomas When Compared to Desogestrel and Goserelin NCT01738724	Drug: Dienogest Drug: Goserelin Drug: Desogestrel	University of Sao Paulo Other	1/1/2013; 12/1/2013 Not Yet Recruiting, No Results Available	63
GnRH Agonist Pretreatment in Hysteroscopic Myomectomy NCT01873378	Drug: Triptorelin 3.75 mg	Azienda Ospedaliera S. Maria della Misericordia	1/1/2013; Null Recruiting, No Results Available	60

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
		Other		
Intra-arterial Lidocaine for Pain Control Post Uterine Fibroid Embolization NCT02293447	Drug: Lidocaine per-embolization	University Health Network, Toronto	11/1/2014; 4/1/2016	60
	Drug: Lidocaine post-embolization	Other	Recruiting, No Results Available	
Vasopressin Versus Epinephrine in Myomectomy NCT01861015	Drug: Epinephrine	CHA University	5/1/2013; 4/1/2016	60
	Drug: Vasopressin	Other	Recruiting, No Results Available	
Misoprostol for Reduction of Blood Loss During Fibroid Surgery NCT02209545	Drug: Misoprostol	Northwestern University	10/1/2014; 5/1/2018	50
	Drug: Placebo	Other	Recruiting, No Results Available	
A Multi-Center, Parallel Design, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of 6 and 12 mg Proellex® (Telapristone Acetate) Administered Orally in the Treatment of Premenopausal Women With Confirmed Symptomatic Uterine Fibroids NCT02301897	Drug: Telapristone Acetate	Repros Therapeutics Inc.	12/1/2014; 12/1/2016	45
	Drug: Placebo	Industry	Recruiting, No Results Available	
A Phase 2, Study to Evaluate the Safety and Efficacy Proellex® (Telapristone Acetate) Administered Vaginally in the Treatment of Uterine Fibroids NCT02323646	Drug: Telapristone Acetate (Proellex®)	Repros Therapeutics Inc.	12/1/2014; 12/1/2016	45
		Industry	Recruiting, No Results Available	
Ulipristal Acetate for the Preoperative Management of Hypoechoic Cellular Leiomyomas	Drug: Ulipristal acetate	University Magna Graecia	2/1/2015; 9/1/2017	42
	Drug: Leuprolide acetate		Recruiting, No Results	

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
NCT02361905		Other	Available	
Clinical Trial of Uterine Artery Embolization for Uterine Leiomyoma	Procedure: Interventional radiological or surgical management	Sun Yat-sen University Other	1/1/2008; 12/1/2018 Enrolling By Invitation, No Results Available	900
NCT00821275				
Post Market TRUST - U.S.A. Study	Procedure: Global Fibroid Ablation (GFA) Procedure: Abdominal or Laparoscopic Myomectomy Procedure: Uterine Artery Embolization (UAE)	Halt Medical, Inc. Industry	6/1/2014; 12/1/2021 Recruiting, No Results Available	300
NCT02163525				
Post Market TRUST Study	Procedure: Global Fibroid Ablation (GFA) Procedure: Abdominal or Laparoscopic Myomectomy Procedure: Uterine Artery Embolization (UAE)	Halt Medical, Inc. Industry	12/1/2012; 12/1/2019 Recruiting, No Results Available	260
NCT01563783				
Sonalleve Fibroid Ablation Pivotal Clinical Trial for MR-HIFU of Uterine Fibroids	Device: MRgHIFU system	Philips Healthcare Industry	5/1/2012; 4/1/2019 Active, Not Recruiting, No Results Available	224
NCT01504308				
High Intensity Focused Ultrasound Ablation Virus Myomectomy to Treat Uterine Fibroids	Procedure: High intensity focused ultrasound	Chongqing Medical University Other	9/1/2010; 7/1/2013 Recruiting, No Results Available	220
NCT01239641 (See Ref ID: 793; 804)				

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Uterine Artery Embolization (UAE) Versus High-Intensity-Focused-Ultrasound (HIFU) for Treatment of Uterine Fibroids NCT01834703	Procedure: Embolization Procedure: HIFU	Chinese University of Hong Kong Prince of Wales Hospital, Shatin, Hong Kong Other	5/1/2009; Null Recruiting, No Results Available	200
The FIRSTT: Comparing MRgFUS (MR-guided Focused Ultrasound) Versus UAE (Uterine Artery Embolization) for Uterine Fibroids NCT00995878	Procedure: Focused ultrasound (MRgFUS) Procedure: Uterine artery embolization (UAE)	Mayo Clinic Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Other, NIH	10/1/2009; 12/1/2015 Active, Not Recruiting, No Results Available	180
Sonography Guided Transcervical Ablation of Uterine Fibroids NCT02228174	Device: Intrauterine Ultrasound-Guided Radiofrequency Ablation System	Gynesonics Industry	10/1/2014; 4/1/2019 Recruiting, No Results Available	147
Laparoscopic Radiofrequency Ablation (RFA) of Symptomatic Uterine Fibroids NCT00874029	Device: Halt Procedure	Halt Medical, Inc Industry	3/1/2009; 3/1/2014 Completed, Has Results	137
China Clinical Trial for Therapeutic MR-HIFU Ablation of Uterine Fibroids NCT01588899	Device: MRgHIFU system	Philips Healthcare Industry	5/1/2012; 6/1/2015 Active, Not Recruiting, No Results Available	110
ExAblate UF V2 System for the Treatment of Symptomatic Uterine Fibroids	Device: ExAblate Treatment UF V2	InSightec	5/1/2012; 4/1/2015 Recruiting, No Results	106

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
NCT01285960		Industry	Available	
Diffusion -and Perfusion Weighted MRI for Response Prediction of Symptomatic Leiomyomas Following Uterine Artery Embolization	Procedure: Diffusion -and perfusion weighted MRI including IV contrast agent injection	Universitaire Ziekenhuizen Leuven Other	1/1/2012; 12/1/2016 Recruiting, No Results Available	100
NCT01514617				
Uterine Leiomyoma Treatment With Radiofrequency Ablation	Procedure: Radiofrequency ablation	University of California Other	7/1/2013; Null Recruiting, No Results Available	100
NCT01840124				
Clinical Study of the Mirabilis High-Intensity Focused Ultrasound System for Non-Invasive Treatment of Uterine Fibroids	Device: Mirabilis High-Intensity Focused Ultrasound Treatment System	Mirabilis Medica, Inc. Industry	1/1/2011; Null Active, Not Recruiting, No Results Available	80
NCT01946178				
Uterine Fibroid Embolization- Long Term Follow up and Technical Perspectives	Procedure: Embolization	Odense University Hospital Other	11/1/2013; 11/1/2015 Recruiting, No Results Available	60
NCT01852734				
Laparoscopic Uterine Sparing Techniques Outcomes and Reinterventions	Procedure: Global Fibroid Ablation	Halt Medical, Inc.	11/1/2012; 9/1/2018	50
NCT01750008 (See Ref ID: 392)	Procedure: Myomectomy	Industry	Active, Not Recruiting, No Results Available	
Post Market Evaluation of Acessa With TAG	Device: Acessa Procedure	Halt Medical, Inc. Industry	4/1/2013; 12/1/2015 Recruiting, No Results Available	50
NCT01842789				

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Factors Influencing Volumetric MR-HIFU Ablation of Uterine Fibroids NCT02386137	Device: Contrast-enhancement ultrasound with Sonovue	University Hospital, Bordeaux Other	3/1/2015; 3/1/2017 Not Yet Recruiting, No Results Available	40
Laparoscopic Cryoablation of Uterine Fibroids NCT01735812	Device: IceSense3 system	IceCure Medical Ltd. Industry	12/1/2012; Null Recruiting, No Results Available	30
Clinical Test of the MRgHIFU System on Uterine Fibroids NCT02283502	Device: MRgHIFU system	Chin-Jung Wang National Health Research Institutes, Taiwan Chang Gung Memorial Hospital Other	9/1/2014; 5/1/2015 Recruiting, No Results Available	20
Safety and Effectiveness of OCL 503 in the Treatment of Women With Leiomyomata NCT02410018	Device: OCL 503 (uterine artery embolization)	IMBiotechnologies Ltd. Industry	4/1/2015; 9/1/2015 Recruiting, No Results Available	10
Far Infrared Radiation Treatment for Uterine Fibroids NCT00574418	Procedure: Far Infrared Radiation (5½m to 20½m wavelength)	GAAD Medical Research Institute Inc. Other	1/1/2006; 9/1/2008 Active, Not Recruiting, No Results Available	2
Hysteroscopic Monopolar and Bipolar Resection NCT00323999	Procedure: Hysteroscopic resection of fibroids, polyps and endometrium	Ullevaal University Hospital Other	12/1/2004; 12/1/2007 Recruiting, No Results Available	Null
MyoSure Hysteroscopic Tissue Removal System	Device: MyoSure Tissue	Hologic, Inc.	11/1/2010; 11/1/2013	600

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Registry Study NCT01369758	Removal System	Industry	Active, not recruiting	
Study of Conventional Laparoscopic Hysterectomy Versus Robot-Assisted Laparoscopic Hysterectomy at a Teaching Institution NCT01581905	Procedure: Conventional Laparoscopic Hysterectomy (LH) Procedure: Robot Assisted Hysterectomy	Milton S. Hershey Medical Center Other	3/1/2012; 6/1/2013 Recruiting, No Results Available	400
Single Incision Laparoscopic Surgery (SILS) Versus Conventional Laparoscopic Hysterectomy NCT01483417	Procedure: Single incision Laparoscopic hysterectomy Procedure: Conventional laparoscopic hysterectomy	Samsung Medical Center Other	12/1/2011; 3/1/2013 Recruiting, No Results Available	240
Minimally Invasive Benign Hysterectomy NCT01865929	Procedure: Vaginal or laparoscopic hysterectomy	Region Skane Other	1/1/2010; 12/1/2015 Recruiting, No Results Available	200
Single-port Access Laparoscopic-assisted Vaginal Hysterectomy NCT01048931	Procedure: Single-port LAVH	Taipei Veterans General Hospital, Taiwan National Yang Ming University Other	10/1/2009; 10/1/2010 Recruiting, No Results Available	100
Vaginal vs. Laparoscopic Hysterectomy NCT02059954	Procedure: Hysterectomy	Medical University of Graz Austrian Urogynecology Working Group (AUWG)	1/1/2014; 7/1/2015 Recruiting, No Results Available	100

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
		Other		
HOME Study: Hysteroscopic Office Myomectomy Evaluation NCT01152112	Device: Myomectomy	Hologic, Inc. Industry	6/1/2010; 3/1/2013 Active, Not Recruiting, No Results Available	86
Barbed Suture in Single-port Laparoscopic Myomectomy NCT01984632	Procedure: Single-port laparoscopic myomectomy Procedure: Multi-port laparoscopic myomectomy	CHA University Other	11/1/2013; 11/1/2015 Recruiting, No Results Available	80
Barbed Suture Versus Traditional Suture Material for Laparoscopic Myomectomy NCT01347385	Procedure: Laparoscopic myomectomy with unidirectional barbed suture Procedure: Traditional suture material	Sunnybrook Health Sciences Centre Other	1/1/2012; Null Not Yet Recruiting, No Results Available	80
Surgical Success After Laparoscopic vs Abdominal Hysterectomy NCT01793584	Procedure: Laparoscopic hysterectomy Procedure: Abdominal hysterectomy	University of Texas Southwestern Medical Center Other	2/1/2013; 6/1/2016 Recruiting, No Results Available	75
Laparoscopic Occlusion of Uterine Vessels Compared to Uterine Fibroid Embolization for Treatment of Uterine Fibroids NCT00277680 (See Ref ID: 2303; 3382)	Procedure: Laparoscopic bilateral occlusion of uterine artery Procedure: Radiological embolization (UFE)	Ullevaal University Hospital Oslo University Hospital Other	12/1/2000; 4/1/2010 Active, Not Recruiting, No Results Available	60
Single or Triple Uterine Tourniquet at Myomectomy NCT02392585	Procedure: Single tourniquet Procedure: Triple tourniquet	Ragıp Atakan Al Ataturk University Other	3/1/2015; 5/1/2017 Recruiting, No Results Available	60

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Use of v Care in Abdominal Hysterectomy NCT02371811	Device: Uterine manipulator (v care)	Ain Shams Maternity Hospital Other	2/1/2015; 8/1/2015 Recruiting, No Results Available	60
Laparoscopic Myomectomy Using Barbed or Conventional Sutures NCT02166411	Procedure: Myomectomy using barbed sutures Procedure: Myomectomy using conventional sutures	Cairo University Other	12/1/2013; 12/1/2015 Recruiting, No Results Available	54
Influence of Aromatase Inhibitors and GnRH Analogs to Treat Uterine Leiomyoma by Vaginal Hysterectomy NCT01280045	Procedure: Vaginal hysterectomy	University of Sao Paulo Other	1/1/2011; 1/1/2015 Recruiting, No Results Available	50
Assessment of the Manageability and Safety of ADBLOCK Adhesion Barrier System in Laparoscopic Gynaecological Surgery NCT01745432	Device: ADBLOCK	Terumo Europe N.V. Industry	8/1/2012; 11/1/2014 Active, Not Recruiting, No Results Available	30

Appendix H. Study Outcome Data

Outcome data for Key Question 1 and Key Question 2

We extracted intermediate and final health outcomes from all studies included for KQ 1. We recorded data on 414 discreet outcome measures representing 19 prespecified outcome categories: symptom status; desired fertility status; pregnancy outcomes; sexual function; fibroid characteristics; fibroid recurrence; subsequent treatment for fibroids; satisfaction with outcomes; transfusion; unplanned hysterectomy; perforation of organs; cancer dissemination; other serious adverse events; technical success; conversion to another procedure; estimated intraoperative blood loss; length of stay; readmission / reoperation; return to usual activities. These data will be publically available in the Systematic Review Data Repository (SRDR).

Harms and Serious Adverse Event Data

We extracted the incidence of harms and serious adverse events reported in the studies included in KQ 1. We limited extraction of harms to a prespecified list (see Methods Chapter in Full Report) and recorded the frequency, including “0”, during or after the intervention and at last followup. We recorded the rate as the count of patients with the event per the number of patients available for analysis and treated per protocol unless study authors indicated that intention to treat was used to calculate the incidence of harms. If the count of harms was reported during or after treatment and at last followup and was cumulative, we recorded the count only in the interval in which the event occurred. We organized the tables by intervention category (i.e., medical interventions, procedural interventions, and surgical interventions). We report these data by arm and do not include comparative rates of harms within studies as studies were not designed to capture harms adequately (i.e., studies were not powered to detect differences in harms or did not include sufficient duration of followup). For this same reason, we did not assess the quality of harms reporting within these studies. We report the incidence of transfusion separately from other harms, as transfusion is a common risk of surgical or procedural removal of fibroids (or the uterus) and is of clinical significance in a population at increased risk of anemia due to excessive uterine bleeding caused by leiomyoma. We categorized the following as serious or major adverse events: death, life-threatening complication, deep vein thrombosis, pulmonary embolism, cardiovascular complication, pulmonary complication, uterine artery dissection.

Medical Interventions

Harms reported at the end of medical treatment for uterine fibroids (5 studies)

Author, Year	Intervention	Harm	EOT Incidence	EOT Rate, %
Donnez J et al. (2015) ¹	ulipristal, 10mg	fibroid expulsion, partial ^a	1/205	0.5
		arteriospasm, coronary	1/205	0.5
		cancer, breast	1/205	0.5
		obstruction, small intestine	1/205	0.5
	ulipristal, 5mg	fibroid expulsion, partial	0/215	0
		arteriospasm, coronary	0/215	0
		cancer, breast	0/215	0

		obstruction, small intestine	0/215	0
Eder S et al. (2013) ²	tranexamic acid, 3.9mg	adverse event, treatment emergent	4/232	1.7
Fedele L et al. (1991) ³	buserelin, intranasal	transfusion	0/15	0
Jirecek S et al. (2004) ⁴	raloxifene, 180mg	adverse event, serious (not defined)	0/13	0
Palomba S et al. (2002) ⁵	leuprolide plus placebo	adverse event, serious ^b	0/50	0
	leuprolide plus raloxifene	adverse event, serious ^b	0/50	0

Notes: ^a assessed as possibly related to intervention by study investigators; ^b death, overdose, diagnosis of cancer, or any life-threatening, permanently disabling or requiring hospitalization.

Procedural Interventions

Harms reported during or after procedural intervention for uterine fibroids (16 studies)

Author, Year	Intervention	Harm	EOT Incidence	EOT Rate, %	LFU Incidence	LFU Rate, %
Bilhim T et al. (2011) ⁶	UAE with PVA particles, large	complication, major	1/80	ND	ND	ND
	UAE with PVA particles, small	complication, major	2/80	ND	ND	ND
Hald K et al. (2007) ⁷	uterine artery occlusion, laparoscopic	fibroid expulsion	1/29	3.5	ND	ND
		claudication, buttock	1/29	3.5	ND	ND
		embolism, pulmonary	1/29	3.5	ND	ND
	UAE	fibroid expulsion	5/29	17.2	ND	ND
		claudication, buttock	0/29	0	ND	ND
		embolism, pulmonary	0/29	0	ND	ND
Hehenkamp WJ et al. (2005) ⁸	UAE	sepsis	0/81	0	1/81	1.2
		embolism, pulmonary	1/81	1.2	0/81	0
Jiang N et al. (2014) ⁹	HIFU plus SonoVue + HIFU	complication, major	0/40	0	ND	ND
Jun F et al. (2012) ¹⁰	UAE	complication, major	ND	ND	0/62	0
Manyonda IT et al. (2012) ¹¹	UAE	sepsis, pelvic requiring IV antibiotics	ND	ND	1/67	1.5
Mara M et al. (2006) ¹²	UAE	complication, life threatening	ND	ND	0/30	0
		complication, serious	ND	ND	3/30	10
		dissection, uterine artery	1/30	3.3	ND	ND
Meng X et al. (2010) ¹³	HIFU	complication, major	0/50	0	0/50	0
Orsi F et al. (2015) ¹⁴	HIFU	complication, major	0/16	0	ND	ND
	HIFU plus CEUS	complication, major	0/17	0	ND	ND
Pinto I et al. (2003) ¹⁵	UAE	abscess, intraabdominal	ND	ND	0/40	0
		abscess, surgical wound	ND	ND	0/40	0

Author, Year	Intervention	Harm	EOT Incidence	EOT Rate, %	LFU Incidence	LFU Rate, %
		dissection, uterine artery	2/40	5.0	ND	ND
		perforation, gluteal artery	2/40	5.0	ND	ND
		thrombosis, deep vein	ND	ND	1/40	2.0
Siskin GP et al. (2008) ¹⁶	UAE with PVA microspheres	hysterectomy	ND	ND	1/40	3.7
	UAE with TAG microspheres	hysterectomy	ND	ND	0/26	0
Song YG et al. (2013) ¹⁷	UAE with gelatin sponge particles	complication, major	ND	ND	0/30	0
	UAE with nPVA	complication, major	ND	ND	0/30	0
Spies JB et al. (2004) ¹⁸	UAE with PVA	embolism, pulmonary	0/46	ND	0/46	0
	UAE with TAG microspheres	embolism, pulmonary	1/54	ND	1/54	1.9
Wang X et al. (2013) ¹⁹	HIFU	death	0/48	0	ND	ND
		complication, severe	0/48	0	ND	ND
Yang Z et al. (2014) ²⁰	HIFU	complication, major SIR Class C-F	0/20	0	ND	ND
	HIFU plus ultrasound guided intramural ethanol injection	complication, major SIR Class C-F	0/20	0	ND	ND
Yu SC et al. (2011) ²¹	UAE with PVA	complication, major SIR Class D	ND	ND	2/30	6.6
		ovarian failure, premature	ND	ND	3/29	11.0
	UAE with TAG microspheres	complication, major SIR Class D	ND	ND	0/30	0
		ovarian failure, premature	ND	ND	2/27	7.0

Abbreviations: CEUS=contrast enhanced ultrasound; EOT=end of treatment; LFU=last followup; UAE=uterine artery embolization; PVA=polyvinyl alcohol particles; TAG=tris-acryl gelatin particles; nPVA= ; HIFU=high intensity focused ultrasound; SIR=

Surgical Interventions

Organ injury or perforation rates of surgical interventions for uterine fibroids (8 studies)

Author, Year	Intervention	Harm	Incidence*	Rate, %*
Brucker SY et al. (2014) ²²	ablation, radiofrequency volumetric thermal	injury, bladder, ureter, bowel or vessels	0/25	0
	myomectomy	injury, bladder, ureter, bowel or vessels	0/25	0
Hwang JL et al. (2002) ²³	hysterectomy, abdominal	injury, major organ or vessel	0/30	0
	hysterectomy, laparoscopic assisted vaginal	injury, major organ or vessel	0/30	0
	hysterectomy, vaginal	injury, major organ or vessel	0/30	0
Mara M et al. (2006) ¹²	myomectomy	dissection, uterine artery	0/33	0
Pinto I et al. (2003) ¹⁵	hysterectomy, abdominal	dissection, uterine artery	0/30	0
		perforation, gluteal artery	0/20	0
Seracchioli R et al. (2002) ²⁴	hysterectomy, abdominal	injury, bowel	0/62	0
	hysterectomy, total laparoscopic	injury, bowel	1/60	1.7
Silva-Filho AL et al. (2006) ²⁵	hysterectomy, total abdominal + hysterectomy, vaginal	laceration, bladder	1/60	1.7
Soysal ME et al. (2001) ²⁶	ablation, endometrial roller ball	injury, cervical	1/28	2.1
	ablation, endometrial thermal balloon	injury, cervical	0/45	0
Yen YK et al. (2002) ²⁷	hysterectomy, laparoscopic assisted vaginal	injury, urinary tract	0/32	0
	hysterectomy, laparoscopic assisted vaginal with bipolar coagulation of uterine vessels	injury, urinary tract	0/29	0

Notes: *Intraoperative or postoperative

**Incidence of other serious harms reported during or after surgical intervention for uterine fibroids
(17 studies)**

Author, Year	Intervention	Harm	EOT Incidence	EOT Rate, %	LFU Incidence	LFU Rate,%
Alessandri F et al. (2006) ²⁸	myomectomy, laparoscopic	peritonitis, acute diffuse	1/74	ND	ND	ND
Benassi L et al. (2002) ²⁹	hysterectomy, abdominal	wound infection	2/59	3.4	ND	ND
		embolism, pulmonary	0/60	0	ND	ND
		hematoma, pelvic	3/59	5.1	ND	ND
	hysterectomy, vaginal	wound infection	0/60	0	ND	ND
		embolism, pulmonary	0/60	0	ND	ND
		hematoma, vaginal cuff	2/59	3.3	ND	ND
Brucker SY et al. (2014) ²²	ablation, radiofrequency volumetric thermal	hospitalization, unplanned	1/25	4.0	ND	ND
	myomectomy	hematoma, suprapubic port site	1/25	4.0	ND	ND
Ferrari MM et al. (2000) ³⁰	hysterectomy, laparoscopic assisted vaginal	complication, major	0/31	0	ND	ND
	hysterectomy, vaginal	complication, major	0/31	0	ND	ND
Hehenkamp WJ et al. (2005) ⁸	hysterectomy	sepsis	0/75	0	0/75	0
		embolism, pulmonary	1/75	1.3	0/75	0
Jun F et al. (2012) ¹⁰	hysterectomy or myomectomy	complication, major	ND	ND	4/62	6.0
Manyonda IT et al. (2012) ¹¹	myomectomy	embolism, pulmonary	ND	ND	1/73	1.4
		sepsis, e. coli	ND	ND	1/73	1.4
Mara M et al. (2006) ¹²	myomectomy	complication, life threatening	ND	ND	0/33	0
		complication, serious	ND	ND	1/33	3.0
Meng X et al. (2010) ¹³	ablation, radiofrequency	complication, major	0/50	0	0/50	0
Pinto I et al. (2003) ¹⁵	hysterectomy, abdominal	abscess, intraabdominal	ND	ND	1/20	5.0
		abscess, surgical wound	ND	ND	3/20	15.0
		thrombosis, deep vein	ND	ND	1/20	5.0
Rossetti A et al. (2001) ³¹	myomectomy, abdominal	complication, major or late	0/40	0	ND	ND
	myomectomy, laparoscopic	complication, major or late	0/41	0	ND	ND
Seracchioli R et al. (2002) ²⁴	hysterectomy, abdominal	wound infection	6/62	9.7	ND	ND
	hysterectomy, total laparoscopic	wound infection	0/60	0	ND	ND
Sesti F et al. (2008) ³²	myomectomy, isobaric gasless laparoscopy	complication, major	0/50	0	ND	ND
	myomectomy, minilaparotomy	complication, major	0/50	0	ND	ND

Author, Year	Intervention	Harm	EOT Incidence	EOT Rate, %	LFU Incidence	LFU Rate,%
Tan J et al. (2008) ³³	myomectomy, isobaric gasless laparoscopic assisted minilaparotomy	complication, intraoperative	0/26	0	ND	ND
	myomectomy, isobaric gasless laparoscopy	complication, intraoperative	0/26	0	ND	ND
Tan J et al. (2009) ³⁴	myomectomy, laparoscopic assisted minilaparotomy	complication, intraoperative	0/40	0	ND	ND
	myomectomy, minilaparotomy	complication, intraoperative	0/40	0	ND	ND
Vercellino G et al. (2012) ³⁵	myomectomy	hydronephrosis	1/86	1.2	ND	ND
		cardiac arrhythmia	1/86	1.2	ND	ND
		embolism, pulmonary	1/86	1.2	ND	ND
	myomectomy plus uterine artery clipping	hydronephrosis	1/80	1.3	ND	ND
		sepsis due to pyelonephritis	1/80	1.3	ND	ND
		hernia, trocar site	1/80	1.3	ND	ND
		thrombosis, sinus venous	1/80	1.3	ND	ND
		death	0/52	0	ND	ND
Wang X et al. (2013) ¹⁹	myomectomy	complication, severe	0/52	0	ND	ND

Abbreviations: EOT=end of treatment; LFU=last followup; ND=no data

Transfusion Rates

Transfusion rates during or following myomectomy (11 studies)

Author, Year	Intervention	Count	N	%
Alessandri F et al. (2006) ²⁸	myomectomy, minilaparotomy	0	74	0
Alessandri F et al. (2006) ²⁸	myomectomy, laparoscopic	0	74	0
Ardovino M et al. (2013) ³⁶	myomectomy, laparoscopic standard	0	72	0
Ardovino M et al. (2013) ³⁶	myomectomy, laparoscopic mini-invasive	0	98	0
Cicinelli E et al. (2009) ³⁷	myomectomy, minilaparotomy	0	40	0
Cicinelli E et al. (2009) ³⁷	myomectomy, laparoscopic assisted minilaparotomy	0	40	0
Mara M et al. (2006) ¹²	myomectomy, open or laparoscopic	2	33	6.1
Rossetti A et al. (2001) ³¹	myomectomy, laparoscopic	0	41	0
Rossetti A et al. (2001) ³¹	myomectomy, abdominal	0	40	0
Seracchioli R et al. (2000) ³⁸	myomectomy, laparoscopic	0	66	0
Seracchioli R et al. (2000) ³⁸	myomectomy, abdominal	3	65	4.6
Sesti F et al. (2008) ³²	myomectomy, minilaparotomy	0	50	0
Sesti F et al. (2008) ³²	myomectomy, isobaric gasless laparoscopy	0	50	0
Vercellino G et al. (2012) ³⁵	myomectomy plus uterine artery clipping	0	80	0
Vercellino G et al. (2012) ³⁵	myomectomy, laparoscopic	0	86	0
Wang JJ et al. (2011) ³⁹	myomectomy, gasless laparoscopic	0	194	0
Wang JJ et al. (2011) ³⁹	myomectomy, conventional laparoscopic	6	190	3.2
Wang X et al. (2013) ¹⁹	myomectomy	1	52	1.9
Zhao F et al. (2011) ⁴⁰	myomectomy, loop ligation with vasopressin	0	35	0
Zhao F et al. (2011) ⁴⁰	myomectomy with vasopressin	1	35	2.8
Zhao F et al. (2011) ⁴⁰	myomectomy	5	35	14.3

N is the number analyzed. The number analyzed was equal to the number randomized in all arms. Transfusion counts are intraoperative or postoperative.

Included studies (n=8) that did not report transfusion rate during or following myomectomy

Author, Year	Myomectomy Arm	N
Brucker SY et al. (2014) ²²	myomectomy	25
Casini ML et al. (2006) ⁴¹	myomectomy	92
Liu M et al. (2011) ⁴²	myomectomy with laparoscopic uterine artery occlusion	158
Mais V et al. (1996) ⁴³	myomectomy, laparoscopic	20
Mais V et al. (1996) ⁴³	myomectomy, abdominal	20
Manyonda IT et al. (2012) ¹¹	myomectomy	74
Palomba S et al. (2007) ⁴⁴	myomectomy, minilaparotomy	68
Palomba S et al. (2007) ⁴⁴	myomectomy, laparoscopic	68
Tan J et al. (2008) ³³	myomectomy, isobaric gasless laparoscopy	26
Tan J et al. (2008) ³³	myomectomy, isobaric gasless laparoscopic assisted minilaparotomy	26
Tan J et al. (2009) ³⁴	myomectomy, minilaparotomy	40
Tan J et al. (2009) ³⁴	myomectomy, laparoscopic assisted minilaparotomy	40

Transfusion rates during or following hysterectomy (11 studies)

Author, Year	Hysterectomy	Count	N	%
Benassi L et al. (2002) ²⁹	hysterectomy, abdominal	4	59	6.8
Benassi L et al. (2002) ²⁹	hysterectomy, vaginal	2	60	3.3
Ferrari MM et al. (2000) ³⁰	hysterectomy, laparoscopic assisted vaginal	0	31	0
Ferrari MM et al. (2000) ³⁰	hysterectomy, vaginal	1	31	3
Hehenkamp WJ et al. (2005) ⁸	hysterectomy	10	89	13.3
Hwang JL et al. (2002) ²³	hysterectomy, abdominal	1	30	3.3
Hwang JL et al. (2002) ²³	hysterectomy, laparoscopic assisted vaginal	5	30	16.7
Hwang JL et al. (2002) ²³	hysterectomy, vaginal	1	30	3.3
Pinto I et al. (2003) ¹⁵	hysterectomy, abdominal	4	20	20
Seracchioli R et al. (2002) ²⁴	hysterectomy, abdominal	1	62	1.6
Seracchioli R et al. (2002) ²⁴	hysterectomy, total laparoscopic	0	60	0
Sesti F et al. (2008) ⁴⁵	hysterectomy, laparoscopic assisted vaginal	0	40	0
Sesti F et al. (2008) ⁴⁵	hysterectomy, vaginal	0	40	0
Sesti F et al. (2014) ⁴⁶	hysterectomy, laparoscopic assisted vaginal	2	36	5.6
Sesti F et al. (2014) ⁴⁶	hysterectomy, total laparoscopic	0	36	0
Sesti F et al. (2014) ⁴⁶	hysterectomy, vaginal	0	36	0
Silva-Filho AL et al. (2006) ²⁵	hysterectomy, total abdominal + hysterectomy, vaginal*	1	60	1.7
Soriano D et al. (2001) ⁴⁷	hysterectomy, laparoscopic assisted vaginal	1	40	2.7
Soriano D et al. (2001) ⁴⁷	hysterectomy, vaginal	1	40	2.5
Yen YK et al. (2002) ²⁷	hysterectomy, laparoscopic assisted vaginal	2	32	6.3
Yen YK et al. (2002) ²⁷	hysterectomy, laparoscopic assisted vaginal with bipolar coagulation of uterine vessels	1	29	3.4

N is the number analyzed. The number analyzed was equal to the number randomized in all arms. *One study reported transfusion counts for both groups. Transfusion counts are intraoperative or postoperative.

Included studies that did not report transfusion rate during or following hysterectomy (3 studies)

Author, Year	Hysterectomy	N
Liu M et al. (2011) ⁴²	hysterectomy, intrafascial supracervical	174
Parazzini F et al. (1999) ⁴⁸	hysterectomy	13
Ruuskanen A et al. (2010) ⁴⁹	hysterectomy	30

Transfusion rates during or following uterine artery embolism, occlusion, or HIFU (5 studies)

Author, Year	UAE/ UAO	Count	N	%
Hehenkamp WJ et al. (2005) ⁸	UAE	0	88	0
Mara M et al. (2006) ¹²	UAE	0	30	0
Mara M et al. (2008) ⁵⁰	UAE	0	58	0
Pinto I et al. (2003) ¹⁵	UAE	0	40	0
Wang X et al. (2013) ¹⁹	HIFU	0	48	0

Abbreviations: UAE=uterine artery embolization; HIFU=high intensity focused ultrasound

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Data extracted for Key Question 3

Citation	Design	N	Age, Mean	Age, SD	LMS	LMS Rate
Adelusola KA, Ogunniyi SO (2001) ¹	Retrospective	177	NR	NR	0	0/177
Ahmed AA, Stachurski J, Aziz EA, et al. (2002) ²	Prospective	10	NR	NR	0	0/10
Angle HS, Cohen SM, Hidlebaugh D (1995) ³	Retrospective	41	41	NR	0	0/41
Balgobin S, Maldonado PA, Chin K, et al. (2016) ⁴	Retrospective	1629	46	11.3	0	0/435
Banaczek Z, Sikora K, Lewandowska-Andruszuk I (2004) ⁵	Retrospective	309	44.5	NR	0	0/309
Barbieri RL, Dilena M, Chumas J, et al. (1993) ⁶	RCT	20	33.7	NR	0	0/20
Begum S, Khan S (2004) ⁷	Prospective	91	NR	NR	0	0/91
Bernard JP, Rizk E, Camatte S, et al. (2001) ⁸	Prospective	75	NR	NR	0	0/75
Betjes HE, Hanstede MM, Emanuel MH, et al. (2009) ⁹	Retrospective	539	44.3	NR	0	0/539
Birsan A, Deval B, Detchev R, et al. (2003) ¹⁰	Prospective	24	NR	NR	0	0/24
Bojahr B, De Wilde RL, Tchartchian G (2015) ¹¹	Retrospective	10731	NR	NR	2	2/10731
Brohl AS, Li L, Andikyan V, et al. (2015) ¹²	Retrospective	2075	38.3	6.1	2	2/2075
Bronz L, Suter T, Rusca T (1997) ¹³	Prospective	25	NR	NR	0	0/25
Brown J, Taylor K, Ramirez PT, et al. (2015) ¹⁴	Retrospective	808	NR	NR	1	1/808
Butt JL, Jeffery ST, Van der Spuy ZM (2012) ¹⁵	Retrospective	106	NR	NR	0	0/106
Campo S, Campo V, Gambadauro P (2005) ¹⁶	Prospective	80	NR	NR	0	0/80
Chen SY, Chang DY, Sheu BC, et al. (2008) ¹⁷	Prospective	136	NR	NR	0	0/136
Cicinelli E, Romano F, Anastasio PS, et al. (1995) ¹⁸	Prospective	11	NR	NR	0	0/11
Clark Donat L, Clark M, Tower AM, et al. (2015) ¹⁹	Retrospective	64	48.5	7.87	0	0/64
Colgan TJ, Pendergast S, LeBlanc M (1993) ²⁰	Retrospective	77	36.9	NR	0	0/77
Cormio G, Loizzi V, Ceci O, et al. (2015) ²¹	Retrospective	588	NR	NR	3	3/588
Corson SL, Brooks PG (1991) ²²	Retrospective	92	40.1	NR	2	2/92
Crescini C (1993) ²³	Prospective	25	NR	NR	0	0/25
Dayoub N (2014) ²⁴	Retrospective	137	36	NR	0	0/137
De Falco M, Staibano S, Mascolo M, et al. (2009) ²⁵	RCT	62	37.3	NR	0	0/62
Deligdisch L, Hirschmann S, Altchek A (1997) ²⁶	Retrospective	60	NR	NR	0	0/60
Di Lieto A, De Falco M, Mansueto G, et al. (2005) ²⁷	RCT	70	36.8	NR	0	0/70
Dijkhuizen FP, De Vries LD, Mol BW, et al. (2000) ²⁸	Prospective	9	NR	NR	0	0/9
Dundr P, Mara M, Maskova J, et al. (2006) ²⁹	Retrospective	20	NR	NR	0	0/20

Citation	Design	N	Age, Mean	Age, SD	LMS	LMS Rate
El-Mowafi D, Madkour W, Lall C, et al. (2004) ³⁰	Retrospective	165	45.8	NR	0	0/165
Emanuel MH, Wamsteker K (2005) ³¹	Retrospective	28	NR	NR	0	0/28
Emanuel MH, Wamsteker K, Hart AA, et al. (1999) ³²	Retrospective	285	NR	NR	1	1/285
Fanfani F, Fagotti A, Bifulco G, et al. (2005) ³³	Prospective	213	NR	NR	0	0/213
Fedele L, Bianchi S, Dorta M, et al. (1991) ³⁴	Prospective	71	NR	NR	0	0/71
Ferrari MM, Berlanda N, Mezzopane R, et al. (2000) ³⁵	RCT	62	NR	NR	0	0/62
Fukuda M, Shimizu T, Fukuda K, et al. (1993) ³⁶	Retrospective	20	NR	NR	0	0/20
Garcia CR, Tureck RW (1984) ³⁷	Prospective	17	NR	NR	0	0/17
Gavai M, Hupuczi P, Papp Z (2006) ³⁸	Retrospective	504	33	NR	0	0/504
Gaym A (2004) ³⁹	Retrospective	588	38.5	NR	0	0/588
Goldrath MH (1990) ⁴⁰	Retrospective	151	NR	NR	1	1/151
Gowri M, Mala G, Murthy S, et al. (2013) ⁴¹	Retrospective	259	NR	NR	0	0/259
Grigoriadis C, Papaconstantinou E, Mellou A, et al. (2012) ⁴²	Retrospective	10	38.2	NR	0	0/10
Gurung G, Pradhan N, Rana SRA (2015) ⁴³	Retrospective	40	NR	NR	0	0/40
Hallez JP (1995) ⁴⁴	Retrospective	284	NR	NR	0	0/284
Hanafi M (2005) ⁴⁵	Retrospective	145	NR	NR	0	0/145
Hanafi M (2013) ⁴⁶	Retrospective	134	43.7	NR	0	0/134
Harmanli OH, Bevilacqua SA, Dandolu V, et al. (2005) ⁴⁷	Retrospective	333	44.2	NR	0	0/333
Hasson HM, Rotman C, Rana N, et al. (1992) ⁴⁸	Retrospective	56	37.2	NR	0	0/56
Hasson HM, Rotman C, Rana N, et al. (1993) ⁴⁹	Retrospective	22	40.4	NR	0	0/22
Hoffman MS, DeCesare S, Kalter C (1994) ⁵⁰	Prospective	47	41.9	NR	0	0/47
Huang JQ, Lathi RB, Lemire M, et al. (2010) ⁵¹	Retrospective	131	41	NR	0	0/131
Jansen FW, de Kroon CD, van Dongen H, et al. (2006) ⁵²	Prospective	89	43.8	NR	0	0/89
Jha R, Pant AD, Jha A, et al. (2006) ⁵³	Retrospective	55	37.6	NR	0	0/55
Johns DA, Diamond MP (1994) ⁵⁴	Retrospective	11	39.2	NR	0	0/55
Kafy S, Huang JY, Al-Sunaidi M, et al. (2006) ⁵⁵	Retrospective	934	59.6	NR	0	0/934
Kalogiannidis I, Prapas N, Xiromeritis P, et al. (2010) ⁵⁶	Prospective	75	34.8	4.5	0	0/75
Kamikabeya TS, Etchebehere RM, Nomelini RS, et al. (2010) ⁵⁷	Retrospective	1364	NR	NR	1	1/1364
Kiltz RJ, Rutgers J, Phillips J, et al. (1994) ⁵⁸	Prospective	28	31	1.8	0	0/28
Kohama T, Hashimoto S, Ueno H, et al. (1997) ⁵⁹	Prospective	25	NR	NR	0	0/25
Kuzel D, Toth D, Fucikova Z, et al. (1999) ⁶⁰	Prospective	45	NR	NR	0	0/45
Landi S, Zaccoletti R, Ferrari L, et al. (2001) ⁶¹	Prospective	368	NR	NR	0	0/368
Laughead MK, Stones LM (1997) ⁶²	Prospective	8	NR	NR	0	0/8
Leibsohn S, d'Ablaing G, Mishell DR, Jr., et al. (1990) ⁶³	Retrospective	1429	NR	NR	7	7/1429

Citation	Design	N	Age, Mean	Age, SD	LMS	LMS Rate
Leung F, Terzibachian JJ, Gay C, et al. (2009) ⁶⁴	Retrospective	1297	48	NR	3	3/1297
Levens ED, Wesley R, Premkumar A, et al. (2009) ⁶⁵	RCT	18	NR	NR	0	0/18
Lieng M, Berner E, Busund B (2015) ⁶⁶	Retrospective	4791	61.2	12.3	6	6/4771
Lim SS, Sockalingam JK, Tan PC (2008) ⁶⁷	RCT	66	46.5	NR	0	0/66
Litta P, Fantinato S, Calonaci F, et al. (2010) ⁶⁸	RCT	160	37.34	NR	0	0/160
Liu L, Li Y, Xu H, et al. (2011) ⁶⁹	Prospective	167	NR	NR	0	0/167
Liu WM, Tzeng CR, Yi-Jen C, et al. (2004) ⁷⁰	Prospective	486	NR	NR	0	0/486
Lyons TL, Adolph AJ, Winer WK (2004) ⁷¹	Retrospective	54	47.3	NR	0	0/54
MacKenzie IZ, Naish C, Rees M, et al. (2004) ⁷²	Retrospective	118	47.5	NR	0	0/118
Mais V, Ajossa S, Guerriero S, et al. (1996) ⁷³	RCT	40	NR	NR	0	0/40
Mansour FW, Kives S, Urbach DR, et al. (2012) ⁷⁴	Retrospective	59	34.7	NR	0	0/59
Mara M, Fucikova Z, Kuzel D, et al. (2006) ⁷⁵	Prospective	80	33.5	NR	0	0/80
Marana R, Busacca M, Zupi E, et al. (1999) ⁷⁶	RCT	90	NR	NR	0	0/90
Mecke H, Wallas F, Brocker A, et al. (1995) ⁷⁷	Retrospective	215	36	NR	0	0/215
Mettler L, Alvarez-Rodas E, Semm K (1995) ⁷⁸	Retrospective	500	43.2	NR	1	1/500
Milad MP, Morrison K, Sokol A, et al. (2001) ⁷⁹	Prospective	69	43.9	NR	0	0/69
Miskry T, Magos A (2003) ⁸⁰	RCT	36	NR	NR	0	0/36
Modupeola S, Adesiyun A, Agunbiade O, et al. (2009) ⁸¹	Retrospective	196	44.6	NR	0	0/196
Moghadam R, Lathi RB, Shahmohamady B, et al. (2006) ⁸²	Retrospective	144	41	NR	0	0/144
Muhammad Z, Ibrahaim S, Agu O (2009) ⁸³	Retrospective	78	46.6	NR	0	0/78
Munoz JL, Jimenez JS, Hernandez C, et al. (2003) ⁸⁴	Retrospective	120	44.8	NR	0	0/120
Nezhat F, Nezhat CH, Admon D, et al. (1995) ⁸⁵	Retrospective	28	NR	NR	0	0/28
Obed JY, Bako B, Usman JD, et al. (2011) ⁸⁶	Prospective	331	30.1	NR	0	0/331
O'Hanlan KA, Dibble SL, Garnier AC, et al. (2007) ⁸⁷	Retrospective	258	50	NR	0	0/258
Okezie O, Ezegwui HU (2006) ⁸⁸	Retrospective	190	NR	NR	0	0/190
Ouldamer L, Rossard L, Arbion F, et al. (2014) ⁸⁹	Retrospective	709	49.5	NR	0	0/709
Palomba S, Orio F, Jr., Russo T, et al. (2005) ⁹⁰	RCT	40	53.4	NR	0	0/40
Palomba S, Zupi E, Falbo A, et al. (2010) ⁹¹	Prospective	30	30.2	NR	0	0/30
Palomba S, Zupi E, Russo T, et al. (2007) ⁹²	RCT	136	NR	NR	0	0/136
Parker WH, Fu YS, Berek JS (1994) ⁹³	Retrospective	1332	NR	NR	1	1/1332
Paul GP, Naik SA, Madhu KN, et al. (2010) ⁹⁴	Retrospective	1001	32.6	NR	1	1/1001
Perveen S, Tayyab S (2008) ⁹⁵	Retrospective	20	NR	NR	0	0/20
Phillips DR, Nathanson HG, Milim SJ, et al. (1995) ⁹⁶	Prospective	38	NR	NR	0	0/38
Picerno TM, Wasson MN, Gonzalez Rios AR,	Retrospective	1004	45.7	NR	0	0/258

Citation	Design	N	Age, Mean	Age, SD	LMS	LMS Rate
et al. (2016) ⁹⁷						
Polena V, Mergui JL, Perrot N, et al. (2007) ⁹⁸	Retrospective	235	47.9	NR	0	0/235
Pron G, Mocarski E, Cohen M, et al. (2003) ⁹⁹	Prospective	8	NR	NR	0	0/8
Radosa MP, Owsianowski Z, Mothes A, et al. (2014) ¹⁰⁰	Retrospective	221	37.9	NR	0	0/221
Raine-Bennett T, Tucker LY, Zaritsky E, et al. (2016) ¹⁰¹	Pop based cohort	34603	NR	NR	172	172/34603
Rein MS, Friedman AJ, Stuart JM, et al. (1990) ¹⁰²	RCT	20	NR	NR	0	0/20
Reiter RC, Wagner PL, Gambone JC (1992) ¹⁰³	Retrospective	104	41.5	NR	0	0/104
Rodriguez AM, Asoglu MR, Sak ME, et al. (2015) ¹⁰⁴	Retrospective	13964	40.9	7	19	19/13964
Rosenblatt P, Makai G, DiSciullo A (2010) ¹⁰⁵	Retrospective	24	50.2	NR	0	0/24
Rovio PH, Helin R, Heinonen PK (2009) ¹⁰⁶	Retrospective	53	44.7	NR	0	0/53
Rutgers JL, Spong CY, Sinow R, et al. (1995) ¹⁰⁷	RCT	22	38	NR	0	0/22
Sahagun Quevedo JA, Perez Ruiz JC, Cherem B, et al. (1994) ¹⁰⁸	Retrospective	594	NR	NR	0	0/594
Sayyah-Melli M, Tehrani-Gadim S, Dastranj-Tabrizi A, et al. (2009) ¹⁰⁹	RCT	23	39.67	NR	0	0/23
Schutz K, Possover M, Merker A, et al. (2002) ¹¹⁰	RCT	48	NR	NR	0	0/48
Seidman MA, Oduseyo T, Muto MG, et al. (2012) ¹¹¹	Retrospective	1091	NR	NR	1	1/1091
Seki K, Hoshihara T, Nagata I (1992) ¹¹²	Retrospective	1886	45.5	NR	7	7/1886
Seracchioli R, Venturoli S, Vianello F, et al. (2002) ¹¹³	RCT	122	46.3	NR	0	0/122
Shen CC, Wu MP, Kung FT, et al. (2003) ¹¹⁴	Retrospective	1521	45.5	NR	0	0/1521
Shergill SK, Shergill HK, Gupta M, et al. (2002) ¹¹⁵	RCT	34	NR	NR	0	0/34
Sikora-Szczęśniak DL, Sikora W, Szczęśniak G ¹¹⁶	Retrospective	294	45.6	NR	0	0/294
Silva BA, Falcone T, Bradley L, et al. (2000) ¹¹⁷	Prospective	39	37	NR	0	0/37
Silva BA, Falcone T, Bradley L, et al. (2000) ¹¹⁷	Retrospective	37	37	NR	0	0/37
Sinha R, Hegde A, Mahajan C, et al. (2008) ¹¹⁸	Prospective	505	34.44	NR	2	2/505
Takamizawa S, Minakami H, Usui R, et al. (1999) ¹¹⁹	Retrospective	923	44.5	NR	1	1/923
Tan J, Sun Y, Dai H, et al. (2008) ¹²⁰	RCT	52	NR	NR	0	0/52
Tan J, Sun Y, Zhong B, et al. (2009) ¹²¹	RCT	80	36.3	NR	0	0/80
Tan-Kim J, Hartzell KA, Reinsch CS, et al. (2015) ¹²²	Retrospective	3523	46	6	3	3/941
Theben JU, Schellong AR, Altgassen C, et al. (2013) ¹²³	Retrospective	1132	45.9	NR	2	2/1132
Tinelli A, Hurst BS, Hudelist G, et al. (2012) ¹²⁴	Prospective	235	NR	NR	0	0/235
Uccella S, Cromi A, Serati M, et al. (2014) ¹²⁵	Retrospective	71	48	NR	0	0/71
Ueki M, Okamoto Y, Tsurunaga T, et al.	Retrospective	230	42.5	NR	0	0/230

Citation	Design	N	Age, Mean	Age, SD	LMS	LMS Rate
(1995) ¹²⁶						
van Dongen H, Emanuel MH, Wolterbeek R, et al. (2008) ¹²⁷	RCT	22	48.2	NR	0	0/22
Vaniova Klimentova D, Braila AD, Simionescu C, et al. (2012) ¹²⁸	Retrospective	959	NR	NR	0	0/959
Varma R, Soneja H, Clark TJ, et al. (2009) ¹²⁹	Prospective	92	NR	NR	1	1/92
Venkatesan AM, Partanen A, Pulanic TK, et al. (2012) ¹³⁰	Prospective	9	NR	NR	0	0/9
Walid MS, Heaton RL (2010) ¹³¹	Retrospective	41	NR	NR	0	0/41
Wamsteker K, Emanuel MH, de Kruif JH (1993) ¹³²	Prospective	51	NR	NR	0	0/51
Wang CJ, Soong YK, Lee CL (2007) ¹³³	Prospective	18	NR	NR	0	0/18
West S, Ruiz R, Parker WH (2006) ¹³⁴	Retrospective	91	40	NR	0	0/91
Widrich T, Bradley LD, Mitchinson AR, et al. (1996) ¹³⁵	Prospective	6	NR	NR	0	0/6
Williams AR, Critchley HO, Osei J, et al. (2007) ¹³⁶	RCT	33	NR	NR	0	0/33
Williams CD, Marshburn PB (1998) ¹³⁷	Prospective	5	38.5	NR	0	0/5
Wortman M, Dagget A (1995) ¹³⁸	Retrospective	75	43.2	NR	0	0/75
Yen YK, Liu WM, Yuan CC, et al. (2002) ¹³⁹	RCT	64	NR	NR	0	0/64
Ylikorkala O, Tiitinen A, Hulkko S, et al. (1995) ¹⁴⁰	RCT	101	43	NR	0	0/101
Yoo EH, Lee PI, Huh CY, et al. (2007) ¹⁴¹	Retrospective	512	33	NR	0	0/512
Yoon HJ, Kyung MS, Jung US, et al. (2007) ¹⁴²	Retrospective	51	34.9	NR	0	0/51
Zhang J, Li T, Zhang J, et al. (2016) ¹⁴³	Retrospective	3021	47.88	6.2	5	5/3021
Zhang J, Zhang J, Dai Y, et al. (2015) ¹⁴⁴	Retrospective	4248	NR	NR	1	1/4248
Zhao WC, Bi FF, Li D, et al. (2015) ¹⁴⁵	Retrospective	10248	48.2	7.64	13	13/10248
Zhu L, Lang JH, Liu CY, et al. (2009) ¹⁴⁶	RCT	101	NR	NR	0	0/101
Zullo F, Palomba S, Corea D, et al. (2004) ¹⁴⁷	RCT	60	28.2	NR	0	0/60

Patient Data Extracted from Studies for Key Question 4

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
Einstein MH et al., 2008 ¹⁴⁸ (5)	Benign	LSC SCH	Yes	Yes	I	No	30	NED	ND	ND	
	Benign	LMYO M	Yes	Yes	I to III	Yes	61	NED	ND	ND	
	Benign	SCH	Yes	No	I to III	Yes	31	AWD	ND	ND	
	Benign	SCH BSO	No	No	I	No	37	NED	ND	ND	

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
	Benign	SCH BSO	No	No	I to IV	Yes	6	AWD	ND	ND	
Kamikabe ya TS et al., 2010 ⁵⁷ (1)	Benign	TAH BSO	No	No	T3 N1 M1	No	2	Died	ND	Post	
Takamizawa S et al., 1999 ¹¹⁹ (1)	Benign	TAH	No	No	NR	NR	132	NED	NR	NR	Received chemo as treatment
Oduyebo T et al., 2014 ¹⁴⁹ (15)	Benign	LSC SCH	Yes	Yes	I	No	27	NED	ND	ND	
	Benign	LSC SCH	Yes	Yes	I	No	38	NED	ND	ND	
	Benign	LMYO M	Yes	Yes	I	No	48.7	NED	ND	ND	
	Benign	LSC SCH	Yes	Yes	IV	NA	3	Died	ND	ND	
	Benign	LAVH	Yes	No	ND	NA	72	AWD	ND	ND	
	Benign	LMYO M	Yes	Yes	I to III	Yes	37.5	Died	ND	ND	
	Benign	LSC SCH	Yes	Yes	III to IV	Yes	5.1	Died	ND	ND	
	Benign	LSC SCH	Yes	Yes	ND	NA	48	Died	ND	ND	
	Benign	LSC SCH	Yes	Yes	I	No	20.2	NED	ND	ND	
	Benign	TVH	Yes	No	I	NA	26	NED	ND	ND	
	Benign	TVH	Yes	No	I	NA	1.8	NED	ND	ND	
	Benign	Roboti c TLH	Yes	Yes	I	NA	15.3	NED	ND	ND	
	Benign	LSC HYST	Yes	No	ND	NA	30.4	Died	ND	ND	
	Benign	LAVH	Yes	No	I	No	4.5	NED	ND	ND	
	Benign	LSC SCH	NR	NR	I to III	Yes	8.3	AWD	ND	ND	
Graebe K et al., 2015 ¹⁵⁰ (3)	Benign	MIS HYST	Yes	Yes	I to abdominal	Yes	8	AWD	NR	Pre	Menorrhagia
	Benign	MIS HYST	Yes	Yes	I to abdominal	Yes	13	AWD	NR	Pre	Menorrhagia
	Poss Malig	MIS HYST	Yes	Yes	NR	NR	NR	NR	NR	Pre	Menorrhagia, MRI cannot rule out malignancy

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
Tan-Kim J et al., 2014 ¹⁵¹ (3)	Benign	LSC HYST	Yes	Yes	I-II initial	No	31	NED	51	Post	
	Benign	LSC HYST	Yes	Yes	0	Yes	51	NED	41	Pre	Mass a staging years later
	Benign	LSC HYST	Yes	Yes	0	Yes	36	Died	48	Pre	Mass a staging years later
Lieng M et al., 2015 ⁶⁶ (25)	Malign	Staging	No	No	NR	NR	NR	Alive	NR	NR	74% of those with LMS post-menopausal
	Malign	Staging	No	No	NR	NR	NR	Alive	NR	NR	
	Malign	Staging	No	No	NR	NR	NR	Died	NR	NR	
	Malign	Staging	No	No	NR	NR	NR	Died	NR	NR	
	Malign	Staging	No	No	NR	NR	NR	Died	NR	NR	
	Poss Malig	Onc	No	No	NR	NR	NR	Alive	NR	NR	
	Poss Malig	Onc	No	No	NR	NR	NR	Alive	NR	NR	
	Poss Malig	Onc	No	No	NR	NR	NR	Alive	NR	NR	
	Poss Malig	Onc	No	No	NR	NR	NR	Died	NR	NR	
	Poss Malig	Onc	No	No	NR	NR	NR	Died	NR	NR	
	Poss Malig	Onc	No	No	NR	NR	NR	Died	NR	NR	
	Poss Malig	Onc	No	No	NR	NR	NR	Died	NR	NR	
	Poss Malig	Onc	No	No	NR	NR	NR	Died	NR	NR	
	Poss Malig	Onc	No	No	NR	NR	NR	Died	NR	NR	
	Benign	LSC HYST	Yes	Yes	NR	NR	NR	Alive	NR	NR	Had near term reoperation for

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
	Benign	ABD MYO M	Yes	No	NR	NR	NR	Died	NR	NR	staging
	Benign	SAH	No	No	NR	NR	NR	Alive	NR	NR	Had near term reoperation for staging
	Benign	SAH	No	No	NR	NR	NR	Alive	NR	NR	Had near term reoperation for staging
	Benign	SAH	No	No	NR	NR	NR	Died	NR	NR	Had near term reoperation for staging
	Benign	SAH	No	No	NR	NR	NR	Died	NR	NR	Had near term reoperation for staging
Sinha R et al., 2008 ¹¹⁸ (2)	Benign	LSC MYO M	Yes	Yes	NR	NR	42	Alive	NR	Pre	Early reoperation TAH/BSO with 3 to 4 years of followup
	Benign	LSC MYO M	Yes	Yes	NR	NR	42	Alive	NR	Pre	Early reoperation TAH/BSO with 3 to 4 years of followup
Tan A et al., 2015 ¹⁵² (2)	Benign	LSC MYO M	Yes	Yes	NR	NR	34	Died	48	Pre	
	Benign	VAG HYST	Yes	No	NR	NR	21	AWD	38	Pre	
Lin KH et al., 2015 ¹⁵³ (24)	Benign	LSC TVH	Yes	NR	I	NR	24	Alive	49.7	NR	Followup time is median for group
	Benign	LSC TVH	Yes	NR	I	NR	24	Alive	49.7	NR	
	Benign	LSC TVH	Yes	NR	I	NR	24	Alive	49.7	NR	
	Benign	LSC TVH	Yes	NR	I	NR	24	Alive	49.7	NR	
	Benign	LSC TVH	Yes	NR	I	NR	24	Dead	49.7	NR	
	Benign	LSC TVH	Yes	NR	I	NR	24	Dead	49.7	NR	Outcomes not tightly linked to surgery
	Benign	LSC TVH	Yes	NR	I	NR	24	Dead	49.7	NR	
	Benign	LSC	Yes	NR	I	NR	24	Dead	49.7	NR	

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
Seidman MA et al., 2012 ¹¹¹ (7)	Benign	TAH	No	No	I	NR	34	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	34	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	34	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	34	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	34	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	34	Dead	52.7	NR	See adjusted HRs in paper
Zhang J et al., 2015 ¹⁴⁴ (1)	Benign	Varied	Yes	Yes	I	No	38	NED	43	NR	
	Benign	Varied	Yes	Yes	I	No	9	NED	48	NR	
	Benign	Varied	Yes	Yes	I	No	42	Alive	42	NR	
	Benign	Varied	Yes	Yes	I	Yes (late)	27	Dead	58	Post	
	Benign	Varied	Yes	Yes	Periton eal	Yes	17	Dead	47	NR	
	Benign	Varied	Yes	Yes	Periton eal	Yes	39	Alive	49	NR	
	Benign	Varied	Yes	Yes	Periton eal	Yes	29	Dead	68	Post	
Bojahr B et al., 2015 ¹¹ (2)	Benign	ABD MYO M	Yes	No	I	No	58	NED	35	Pre	
	Benign	LSC SCH	Yes	Yes	I	No	137	NED	49	NR	
Theben JU et al., 2013 ¹²³ (2)	Benign	LSC SCH	Yes	NR	I	No	52	NED	43	NR	
	Benign	LSC SCH	Yes	NR	I	No	36	NED	49	NR	
Perri T et al., 2009 ¹⁵⁴ (37)	NR	TAH	No	No	I	NR	72	Alive	48	Post	Median age for TAH group
	NR	TAH	No	No	I	NR	72	Alive	48	Post	Median followup for TAH group
	NR	TAH	No	No	I	NR	72	Alive	48	Post	Proportion Alive/Dead matched - individual data not given
	NR	TAH	No	No	I	NR	72	Alive	48	Post	
	NR	TAH	No	No	I	NR	72	Alive	48	Post	
	NR	TAH	No	No	I	NR	72	Dead	48	Post	
	NR	TAH	No	No	I	NR	72	Dead	48	Post	
	NR	TAH	No	No	I	NR	72	Dead	48	Pre	
	NR	TAH	No	No	I	NR	72	Dead	48	Pre	

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
NR	TAH	No	No	I	NR	72	Dead	48	Pre		
NR	TAH	No	No	I	NR	72	Dead	48	Pre		
NR	TAH	No	No	I	NR	72	Dead	48	Pre		
NR	TAH	No	No	I	NR	72	Dead	48	Pre		
NR	TAH	No	No	I	NR	72	Alive	48	Pre		
NR	TAH	No	No	I	NR	72	Alive	48	Pre		
NR	TAH	No	No	I	NR	72	Alive	48	Pre		
NR	TAH	No	No	I	NR	72	Alive	48	Pre		
NR	TAH	No	No	I	NR	72	Alive	48	Pre		
NR	TAH	No	No	I	NR	72	Alive	48	Pre		
NR	ABD MYO M	Yes	No	I	NR	24	Dead	52	Post	Median age for morcellation group	
NR	ABD MYO M	Yes	No	I	NR	24	Dead	52	Pre	Median followup for morcellation group	
NR	ABD MYO M	Yes	No	I	NR	24	Alive	52	Pre	Proportion Alive/Dead matched - individual data not given	
NR	ABD MYO M	Yes	No	I	NR	24	Alive	52	Pre		
NR	H'SC OPE MYO	Yes	No	I	NR	24	Dead	52	Post		
NR	H'SC OPE MYO	Yes	No	I	NR	24	Dead	52	Pre		
NR	H'SC OPE MYO	Yes	No	I	NR	24	Dead	52	Pre		
NR	H'SC OPE MYO	Yes	No	I	NR	24	Alive	52	Pre		
NR	LSC HYST	Yes	Yes	I	NR	24	Dead	52	Post		
NR	LSC HYST	Yes	Yes	I	NR	24	Dead	52	Pre		
NR	SCH	Yes	No	I	NR	24	Alive	52	Pre		
NR	SCH	Yes	No	I	NR	24	Dead	52	Pre		
NR	SCH	Yes	No	I	NR	24	Dead	52	Post		
NR	SCH	Yes	No	I	NR	24	Alive	52	Post		

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
	NR	TAH UT INJ	Yes	No	I	NR	24	AWD	52	Post	
	NR	TAH UT INJ	Yes	No	I	NR	24	Dead	52	Pre	
Park JY et al., 2011 ¹⁵⁵ (56)	Benign	LSC ASST VH	Yes	NR	I	NR	27	Dead	46.4	Post	Median follow-up times by group
	Benign	LSC ASST VH	Yes	NR	I	NR	27	Dead	46.4	Post	
	Benign	LSC ASST VH	Yes	NR	I	NR	27	Dead	46.4	Post	
	Benign	LSC ASST VH	Yes	NR	I	NR	27	Dead	46.4	Pre	
	Benign	LSC ASST VH	Yes	NR	I	NR	27	Dead	46.4	Pre	
	Benign	LSC ASST VH	Yes	NR	I	NR	27	Dead	46.4	Pre	
	Benign	LSC ASST VH	Yes	NR	I	NR	27	Dead	46.4	Pre	
	Benign	LSC ASST VH	Yes	NR	I	NR	27	AWD	46.4	Pre	
	Benign	LSC ASST VH	Yes	NR	I	NR	27	Alive	46.4	Pre	
	Benign	LSC ASST VH	Yes	NR	I	NR	27	Alive	46.4	Pre	
	Benign	LSC ASST VH	Yes	NR	I	NR	27	Alive	46.4	Pre	
	Benign	LSC ASST VH	Yes	NR	I	NR	27	Alive	46.4	Pre	

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
Benign	Benign	TAH	No	No	I	NR	31	Alive	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Alive	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Alive	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Alive	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Alive	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Alive	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Alive	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Alive	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Alive	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Alive	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Alive	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Dead	47.9	Pre	
	Benign	TAH	No	No	I	NR	31	Dead	47.9	Pre	
	Benign	TAH	No	No	II	NR	31	Dead	47.9	Post	
	Benign	TAH	No	No	II	NR	31	Dead	47.9	Pre	

Notes: Unable to extract data from Morice P., et al. (2003)^{156†(116)}; authors did not report patient level data.

Abbreviations: ABD MYOM = abdominal myomectomy; AWD = alive with disease; BSO = bilateral salpingo-oophorectomy; H'SCOPE MYO = hysteroscopic myomectomy; LAVH = laparoscopic-assisted vaginal hysterectomy; LMYOM = laparoscopic myomectomy with morcellation; LMS = leiomyosarcoma; LSC ASST VH = laparoscopic assisted vaginal hysterectomy; LSC HYST = laparoscopic hysterectomy; LSC MYOM = laparoscopic myomectomy; LSC SCH = Laparoscopic supracervical hysterectomy; malign = malignant; MIS HYST = minimally invasive hysterectomy; MRI = magnetic resonance imaging; NA = not applicable; NED = no evidence of disease; ND = no data; NR = not reported; Onc = oncology; Post = postmenopausal; Poss Malig = possibly malignant; Pre = premenopausal; SAH = supracervical abdominal hysterectomy; SCH = supracervical hysterectomy; TAH = total abdominal hysterectomy; TAH BSO= total abdominal hysterectomy with bilateral salpingo-oophorectomy; TAH UT INJ = total abdominal hysterectomy uterus injured; TLH = total laparoscopic hysterectomy; TVH = total vaginal hysterectomy; VAG HYST = vaginal hysterectomy

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Appendix I: Estimates of Subsequent Treatment for Uterine Fibroids

Estimated probability of subsequent treatment for fibroids following medical management

Next Intervention		None	UAE	IUD	Myomectomy	Hysterectomy	MRgFUS
age	followup						
30	6	0.98 (0.96, 0.99)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.01 (0.00, 0.01)	0.02 (0.01, 0.03)	0.00 (0.00, 0.00)
	12	0.99 (0.98, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.01)	0.00 (0.00, 0.01)	0.00 (0.00, 0.00)
	24	0.99 (0.98, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.01)	0.00 (0.00, 0.00)	0.01 (0.00, 0.00)
40	6	0.99 (0.98, 0.99)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.01)	0.01 (0.01, 0.01)	0.00 (0.00, 0.00)
	12	1.00 (0.99, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)
	24	0.99 (0.99, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)
50	6	0.99 (0.99, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.01 (0.00, 0.01)	0.00 (0.00, 0.00)
	12	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)
	24	0.99 (1.00, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.01 (0.00, 0.00)

Estimated probability of subsequent treatment for fibroids following uterine artery embolization

Next Intervention		None	UAE	IUD	Myomectomy	Hysterectomy	MRgFUS
Age	followup						
30	6	0.59 (0.49, 0.70)	0.01 (0.00, 0.03)	0.00 (0.00, 0.00)	0.40 (0.29, 0.50)	0.00 (0.00, 0.01)	0.00 (0.00, 0.00)
	12	0.60 (0.50, 0.70)	0.01 (0.00, 0.03)	0.00 (0.00, 0.00)	0.39 (0.28, 0.48)	0.00 (0.00, 0.01)	0.00 (0.00, 0.00)
	24	0.62 (0.49, 0.74)	0.01 (0.00, 0.04)	0.00 (0.00, 0.00)	0.36 (0.23, 0.48)	0.01 (0.00, 0.01)	0.00 (0.00, 0.00)
40	6	0.93 (0.91, 0.95)	0.01 (0.01, 0.02)	0.00 (0.00, 0.00)	0.04 (0.02, 0.05)	0.02 (0.01, 0.03)	0.00 (0.00, 0.00)
	12	0.93 (0.91, 0.95)	0.02 (0.01, 0.03)	0.00 (0.00, 0.00)	0.03 (0.02, 0.05)	0.02 (0.01, 0.03)	0.00 (0.00, 0.00)
	24	0.92 (0.89, 0.94)	0.02 (0.01, 0.03)	0.00 (0.00, 0.00)	0.03 (0.02, 0.04)	0.04 (0.02, 0.05)	0.00 (0.00, 0.00)
50	6	0.54 (0.10, 0.87)	0.01 (0.00, 0.02)	0.34 (0.00, 0.86)	0.00 (0.00, 0.00)	0.07 (0.00, 0.14)	0.00 (0.00, 0.00)
	12	0.59 (0.22, 0.86)	0.01 (0.00, 0.03)	0.27 (0.00, 0.69)	0.00 (0.00, 0.00)	0.09 (0.02, 0.18)	0.00 (0.00, 0.00)
	24	0.63 (0.42, 0.83)	0.02 (0.00, 0.03)	0.15 (0.00, 0.40)	0.00 (0.00, 0.00)	0.15 (0.06, 0.28)	0.00 (0.00, 0.00)

Estimated probability of subsequent treatment for fibroids following myomectomy

Next Intervention		None	UAE	IUD	Myomectomy	Hysterectomy	MRgFUS
age	followup						
30	6	0.58 (0.00, 0.97)	0.10 (0.00, 1.00)	0.15 (0.00, 1.00)	0.09 (0.00, 0.37)	0.00 (0.00, 0.01)	0.05 (0.00, 0.37)
	12	0.84 (0.49, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.16 (0.00, 0.50)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)
	24	0.72 (0.25, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.28 (0.00, 0.75)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)
40	6	0.99 (0.98, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.01 (0.00, 0.02)	0.00 (0.00, 0.00)
	12	1.00 (0.99, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.01)	0.00 (0.00, 0.00)
	24	1.00 (0.99, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.01)	0.00 (0.00, 0.01)	0.00 (0.00, 0.00)
50	6	0.40 (0.00, 0.99)	0.13 (0.00, 1.00)	0.09 (0.00, 1.00)	0.00 (0.00, 0.00)	0.04 (0.00, 0.23)	0.11 (0.00, 1.00)
	12	0.85 (0.00, 1.00)	0.05 (0.00, 0.33)	0.03 (0.00, 0.00)	0.00 (0.00, 0.00)	0.02 (0.00, 0.10)	0.03 (0.00, 0.00)
	24	0.99 (0.95, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.01 (0.00, 0.05)	0.00 (0.00, 0.00)

Appendix J. Summary of Existing Systematic Reviews

We included 23 existing systematic reviews of interventions for uterine fibroids.

Medical Interventions

Existing Reviews of Medical Interventions for Uterine Fibroids (8 reviews)

Author, Year	Intervention	Inclusion Criteria	Outcome(s)	# Studies Included	Key Findings
Peitsidis et al. 2014 ¹	Medical -Tranexamic acid	<ul style="list-style-type: none"> Women of reproductive age with symptomatic fibroids Administration of tranexamic acid Literature from 1950 to 2014 	<ul style="list-style-type: none"> Menorrhagia Periprocedural blood loss 	5 studies 349 women; of these 206 patients treated with tranexamic acid and 101 patients allocated to placebo groups	<ul style="list-style-type: none"> Only 5 included studies Presence of bias related to size and location of fibroids Tranexamic acid may reduce blood loss peroperatively in myomectomies
Kamath et al. 2014 ²	Medical -GnRH analogues	<ul style="list-style-type: none"> Women undergoing hysteroscopic resection of submucous fibroids RCTs Literature from 1980 to July 2012 	Menstrual symptoms	2 studies Study 1: 47 patients (24 intervention; 23 control) Study 2: 39 patients (20 intervention; 19 control)	<ul style="list-style-type: none"> Only 2 included studies No significant difference in symptom relief Inadequate evidence to show support for routine use
Chen et al. 2011 ³	Medical -GnRH agonists	<ul style="list-style-type: none"> Comparison of GnRH agonist pretreatment with placebo or no pretreatment RCTs Literature from January 1950 to June 2010 	<ul style="list-style-type: none"> Intraoperative blood loss Transfusion Duration of surgery 	3 RCTs encompassing 7 reports Included 168 women, 85 received GnRH and 83 who did not	<ul style="list-style-type: none"> GnRH pretreatment had no effect on operative time Intraoperative blood loss was statistically lowered
Steinauer et al. 2004 ⁴	Medical -Mifepristone	<ul style="list-style-type: none"> Mifepristone Literature from 1985 to 2002 	Leiomyoma or uterine size	6 studies All before and after clinical trials comparing pretreatment and posttreatment leiomyoma or uterine volume	<ul style="list-style-type: none"> Small sample sizes in studies Mifepristone helped to reduce leiomyoma size Improvement in symptoms
Lethaby et al. 2002 ⁵	Medical -GnRH analogues (GnRHa)	<ul style="list-style-type: none"> GnRHa administered prior to surgery Literature from 1980 to 2000 RCTs 	<ul style="list-style-type: none"> Uterine and fibroid volume Duration of operation Complications 	<ul style="list-style-type: none"> GnRHa vs no therapy (14 studies) GnRHa vs placebo (6 studies) GnRHa vs lynestrenol (1) 	<ul style="list-style-type: none"> Pre- and post-operative hemoglobin and hematocrit significantly improved Reduction in uterine and fibroid volume Pelvic symptoms were

Author, Year	Intervention	Inclusion Criteria	Outcome(s)	# Studies Included	Key Findings
				study)	<p>reduced but with adverse events</p> <ul style="list-style-type: none"> • GnRHa beneficial in correction of preoperative iron deficiency anemia
Deng et al. 2012 ⁶	Medical -Selective estrogen receptor modulators (SERMs)	<ul style="list-style-type: none"> • Women with confirmed uterine fibroids • Women of reproductive age • RCTs 	<ul style="list-style-type: none"> • Fibroid size • Quality of life • Symptoms • Adverse events 	3 studies, number of participants ranged from 25 to 100	<ul style="list-style-type: none"> • Raloxifene used in all included studies • Included studies were of poor quality • Use of SERMs show reduction of fibroid size • No included studies reported quality of life
Song et al. 2013 ⁷	Medical -Aromatase inhibitors	<ul style="list-style-type: none"> • Use of aromatase inhibitors for uterine fibroids • RCTs 	<ul style="list-style-type: none"> • Fibroid size • Symptoms • Adverse events 	1 study with 70 participants	<ul style="list-style-type: none"> • Only 1 included study • No evidence of relief of symptoms • Study failed to report important clinical outcomes
Moroni et al. 2015 ⁸	Medical -Add back therapy for GnRH analogue treatment	<ul style="list-style-type: none"> • Women with symptomatic uterine fibroids • RCTs 	<ul style="list-style-type: none"> • Quality of life • Bone density • Vasomotor symptoms • Uterine volume and bleeding 	14 studies Data extracted from 12 studies with 622 participants	<ul style="list-style-type: none"> • Most (9/12) assessed as high risk of bias • Maximum followup was 6 months • Some evidence that add back with tibolone improves quality of life

Procedural Interventions

Existing Reviews of Procedural Interventions for Uterine Fibroids (2 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
Clark, N et al 2014 ⁹	MRI-guided focused ultrasound	<ul style="list-style-type: none"> • MRgFUS for treatment of uterine fibroids 	<ul style="list-style-type: none"> • Symptoms • Subsequent reproductive outcomes • Pregnancy 	39 (subset of 10 included in meta-analysis) Case reports, case series, reviews and retrospective evaluations	<ul style="list-style-type: none"> • Symptom severity scores improved from baseline 56.3 to 31.0 after 6 months (95% CI: 23.9-38.2) • 35 pregnancies reported • Average time to conception was 8 months after procedure
Gizzo et al, 2014 ¹⁰	MRI-guided focused ultrasound myomectomy	<ul style="list-style-type: none"> • Studies reporting data of myomectomy by MRgFUS 	<ul style="list-style-type: none"> • Number of fibroids treated • Fibroid volume • UFS-QOL • Fertility • Harms 	38 studies including case reports, retrospective and prospective case series (included approximately 2500 women)	<ul style="list-style-type: none"> • Most frequently reported complications skin burns, abdominal pain, sciatic nerve paresthesia or leg pain. • UFS-QOL scores improved at 3, 6 and 12 months following

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
					treatment

Levonorgestrel intrauterine device (IUD) / Levonorgestrel intrauterine system (LNG-IUS)

Systematic Reviews of LNG-IUS (4 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
Jiang W, Shen Q, Chen M, et al. 2014 ¹¹	LNG-IUS	<ul style="list-style-type: none"> Premenopausal women with symptomatic uterine leiomyoma Search dates: database inception through July 2013 	<ul style="list-style-type: none"> Fibroid and bleeding outcomes Adverse effects 	11 studies; sample sizes ranging from 10 to 104	<p>Fibroid and bleeding outcomes</p> <ul style="list-style-type: none"> uterine volume: decreased menstrual blood loss: reduced hemoglobin: increased ferritin: increased hematocrit: increased leiomyoma volume: no change <p>Adverse effects</p> <p>Device expulsion</p> <ul style="list-style-type: none"> increased with leiomyoma size (larger than 3cm) not associated with leiomyoma location <p>Irregular bleeding/ spotting</p> <ul style="list-style-type: none"> Observed at the beginning of the follow-up period and then decreased
Varma R, Sinha D, Gupta JK. 2006 ¹²	LNG-IUS	<ul style="list-style-type: none"> Observational and experimental studies of LNG-IUS Search dates: 1996 to 2005 	<ul style="list-style-type: none"> Fibroid and bleeding outcomes 	3 RCTs; 7 observational studies for fibroids or fibroid related menorrhagia	<p>Fibroid and bleeding outcomes</p> <ul style="list-style-type: none"> menstrual blood loss: decreased 84–90% hemoglobin: increased 2–3 g/dl fibroid size: inconsistent (decreased and no change)
Zapata LB, Whiteman MK, Tepper NK, et al. 2010 ¹³	LNG-IUS	<ul style="list-style-type: none"> Women with uterine fibroids IUD (copper or levonorgestrel-releasing) use and uterine fibroids Search dates: database inception through June 2009 	<ul style="list-style-type: none"> Fibroid and bleeding outcomes Expulsion rates 	11 studies	<p>Fibroid and bleeding outcomes</p> <ul style="list-style-type: none"> menstrual blood loss: decreased (11 studies) among women using IUD hemoglobin, hematocrit and ferritin levels increased <p>LNG-IUD expulsion rates</p> <ul style="list-style-type: none"> women with uterine fibroids: 0–20% (2 cohort studies, fair to poor quality; 6

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
					noncomparative studies) • women without uterine fibroids: 0 - 3% (2 cohort studies, fair to poor quality)
Sangkomka mhang US, Lumbiganon P, Laopaiboon M, et al. 2013 ¹⁴	LNG-IUS	• Premenopausal women with uterine fibroids	• Fibroid symptoms and characteristics • Quality of life • Recurrence • Adverse events • Cost effectiveness	3 RCTs with 187 women	• No evidence of effectiveness of progestogens • Limited evidence of effectiveness of LNG-IUS • Small sample sizes and few studies

Uterine Artery Embolization (UAE)

Existing Reviews of UAE Interventions for Uterine Fibroids (5 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
Das et al, 2014 ¹⁵	UAE, comparison of embolic agents	• Reproductive age women • Uterine artery embolization for uterine fibroids.	• UFS-QOL • Imaging outcomes • Fibroid infarction rate • Fibroid volume	5 RCTs (295 women) 5 non-RCTs (617 women)	• No evidence for superiority of any embolic agent
Martin et al, 2013 ¹⁶	UAE	• Uterine artery embolization	• Complication • Reintervention	8 RCTs with 350 participants 76 non-RCTs with 11,195 participants 41 case studies with 83 participants	• Significantly lower rates of major complications with UAE compared to surgery (2 RCTs) • Increased risk (ORs ranging from 2.7-10.4) of reintervention for UAE (3 RCTs) • UAE failure (4%), fever (4%), and postembolization syndrome (2.9%)
Toor et al, 2012 ¹⁷	UAE	• Women treated with UAE for uterine fibroids • Minimum followup of 1 month	• Complication • Reintervention	54 studies with 8159 participants including 7 RCTs, 37 prospective cohorts and 10 retrospective	• Rate of major complications was 2.9% (95% CI 2.2-3.8%) • The rate of follow up hysterectomy to resolve complication was 0.7% (95% CI 0.5-0.9%) • Reintervention rates were 5.3%
Van der Kooji et al, 2011 ¹⁸	UAE vs surgery	• Premenopausal women with heavy bleeding due to symptomatic fibroids • Controlled trials comparing UAE vs	• Procedure results • Return to activities • Symptom	4 RCTs with 515 participants	• UAE associated with less blood loss, and quicker return to normal activities. • Long-term quality of life results were

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
		surgery	status <ul style="list-style-type: none"> • Quality of life • Complication • Reintervention 		comparable for UAE and surgical groups <ul style="list-style-type: none"> • Higher reintervention rate following UAE
Gupta et al, 2014 ¹⁹	UAE vs medical or surgical comparator	<ul style="list-style-type: none"> • Women with symptomatic uterine fibroids • RCTs comparing UAE to any medical or surgical therapy 	<ul style="list-style-type: none"> • Patient satisfaction • Live birth 	7 RCTs with 793 participants	<ul style="list-style-type: none"> • No differences in patient satisfaction up to 2 or 5 years • Higher rate of reintervention for UAE within 2 years • No differences in risk of major complications • Higher rate of minor complications associated with UAE • Limited data on live births

Uterine Sparing Interventions

Existing Reviews Uterine Sparing Interventions for Uterine Fibroids (1 review)

Author, Year	Intervention	Inclusion Criteria	Outcome(s)	# Studies Included	Key Findings
Panagiotopoulou et al. 2014 ²⁰	Uterine sparing	<ul style="list-style-type: none"> • Premenopausal women with fibroids who wished to preserve their uterus • RCTs • Literature from 1948 to 2013 	<ul style="list-style-type: none"> • Patient satisfaction • Re-intervention rate • Reproductive outcomes • Recovery time • Complications • Length of hospital stay 	5 studies 436 women were included 3 studies comparing UAE with LUAO 2 studies comparing UAE with myomectomy	<ul style="list-style-type: none"> • UAE better patient satisfaction • Evidence of fertility/pregnancy outcomes poor • Myomectomy requires longer hospital stay and recovery time

Surgical Interventions

Existing Reviews of Surgical Interventions for Uterine Fibroids (3 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
Nieboer, et al 2009 ²¹	Hysterectomy (vaginal, abdominal, laparoscopic assisted)	<ul style="list-style-type: none"> Women undergoing hysterectomy for benign disease including uterine fibroids RCTs comparing abdominal, vaginal, and laparoscopic assisted hysterectomy 	<ul style="list-style-type: none"> Return to normal activities Satisfaction and quality of life Intraoperative visceral injury Major complications Operation time Intraoperative complications Costs 	34 RCTs (4495 women) 6 studies specifically included women with symptomatic UF	<ul style="list-style-type: none"> Vaginal hysterectomy associated with faster return to normal activities, fewer infections, and shorter hospital stay compared to abdominal hysterectomy. Laparoscopic assisted vaginal hysterectomy associated with faster return to normal activities, less blood loss, and shorter hospital stay More urinary or bladder injuries in LAVH compared to abdominal hysterectomy Data were not available for many long-term outcomes
Yi et al, 2011 ²²	Myomectomy (vaginal and laparoscopic)	<ul style="list-style-type: none"> RCTs comparing laparoscopic and vaginal myomectomy 	<ul style="list-style-type: none"> Operative outcomes including time, blood loss, length of stay, gas recovery time Major and minor complications 	4 RCTs (466 women)	<ul style="list-style-type: none"> Vaginal myomectomy associated with significantly shorter operation time Other differences in outcomes were not statistically significant Data were limited and unavailable for major complications and long-term outcomes
Bhave Chittawar et al. 2014 ²³	Myomectomy (laparoscopic or hysteroscopic vs open)	<ul style="list-style-type: none"> RCTs comparing myomectomy types in premenopausal women with UF 	<ul style="list-style-type: none"> Primary outcomes: postoperative pain, in-hospital adverse events Secondary outcomes: Length of stay, operating time and recurrence 	9 RCTs (808 women)	<ul style="list-style-type: none"> Laparoscopic myomectomy associated with less postoperative pain and shorter hospital stay No differences noted for recurrence rates between laparoscopic vs open procedures

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